Bulletin of Prosthetics Research

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VETERANS ADMINISTRATION CONFERENCE OF PROSTHETICS AND SENSORY AIDS RESEARCH PROJECT LEADERS

July 20-23, 1974

REHABILITATION INSTITUTE OF CHICAGO
Auditorium, 16th Floor
345 East Superior Street
Chicago, Illinois 60611

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A BASIC THEME OF COOPERATION

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. . . . an editorial

For the first time, an entire issue of the Bulletin is devoted to a single topic—a conference of project leaders of both intramural and contractual projects in the VA prosthetics research program. These leaders, their close associates, and invited guests met in Chicago, July 19-23, 1974, to review the broad VA prosthetics research program, their individual contributions, their interlocking roles, and thus their priorities. The conference used both the lecture demonstrations of plenary sessions and the vigorous interactions of parallel workshops on various specialties to review the state of the art, to critically examine the state of the effort, and then to discuss future needs. As implicit in the conference, some examination of philosophies, guiding policies, and current trends may be in order in this introduction to a series of papers and abstracts condensing 4½ days (and numerous evening hours) of thoughtful discussions.

Some major concepts in prosthetics research are the transition procedure, the clinic team, several forms of specialized prosthetics education, and the need for interdisciplinary contributions. All are aspects of a greater whole. The basic theme of cooperation—of individuals, of disciplines, of intramural and contractual research projects, and of the total VA prosthetics research program with those of other sponsors and with related VA clinical programs—intertwines throughout the entire structure.

One of the characteristics of the broad field of prosthetics research since World War II, has been the transition procedure. Close liaison with the clinical program brings recognition of clinical needs. Research ideas for solving them are carried through successive interations of development, evaluation, and refinement, leading to reevaluation. The new concept is launched through pump-priming purchases in low volume of temporarily expensive test models. Then systematic clinical trials are conducted with assistance of selected clinic teams. Education is launched for the several disciplines typically involved. Eventual

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placement of the item "under contract" with the Veterans Administration then allows nationwide procurement under specific conditions. These centrally guided prosthetics contracts now routinely require fitting under supervision of a VA Qualified Prosthetist. Often they also include additional special requirements, such as specific short, intensive courses at university postgraduate programs to impart to the prosthetist new principles and skills in special techniques. This pattern suggests analogies for other fields.

Similarly, in the fall of 1974 new courses in electronic travel aids for the blind have been launched at Western Michigan University, with the aid of the VA Assistant Chief Medical Director for Academic Affairs and the cooperation of the Chief, Blind Rehabilitation. These courses assist not only in final clinical evaluation of new mobility aids but also in expanding clinical use by both veterans and nonveterans. These aids include two non-VA developments—the Binaural Sensory Aid designed by Prof. Leslie Kay and developed by Wormald Vigilant, Ltd., with the help of the New Zealand government and the simpler ultrasonic Pathsounder designed by Lindsay Russell in conjunction with the MIT Sensory Aids Evaluation and Development Center headed by Prof. Robert W. Mann and supported by Social and Rehabilitation Service. Thus these transitional concepts can be useful, especially in the later and increasingly expensive stages, not only to a developer like Bionic Instruments working under VA research contract on the laser cane but also to developers sponsored by other governmental agencies or by private funds.

The clinic team concept was largely (though not entirely) fostered by the prosthetics research program. The week-long suction socket schools, beginning late in 1947, brought together surgeons and prosthetists, and the followup added therapists. The upper-limb case study at UCLA in 1950-51 refined the prescription and check-out concepts. The upper-limb postgraduate schools at UCLA, beginning with a pilot course for Chicago University-based teams in 1952, continuing routinely for other teams after 1953, and supplemented by a field study operated by New York University, recognized some 85 teams. This team concept soon was widely used by many agencies in the United States; repeated surveys by the National Research Council have shown some 400 prosthetics clinic teams in operation.

The clinic team concept was also introduced into international practice through the International Society for Welfare of Cripples and its successors, especially through their International Prosthetics Courses, beginning in Copenhagen in 1957. The current International Society for Prosthetics and Orthotics appears to assume that interdisciplinary clinic teams are essential for adequate care of patients.

Similarly, interdisciplinary Visual Impairment Service Teams (VIST)

have been developed within the Veterans Administration. Logically this concept of organized interdisciplinary service to the blind and visually handicapped, long used by some pioneers, likewise should spread to other agencies and nations. One may hope that the special educational programs being developed at Western Michigan University on mobility aids for the blind for already-certified orientation and mobility instructors will be expanded for other disciplines and for entire teams. Topics for broader education eventually should include aids to overcome reading and additional problems not only of the totally blind but also of the much larger numbers of visually impaired individuals retaining partial sight.

Not only at the clinic team level in serving specific patients but also at the research and development stage in helping broader categories of patients, interdisciplinary cooperation is important, indeed usually crucial. The goal is to serve real needs, best defined by clinicians in contact with a broad spectrum of patients.

Cooperation between projects, too, is important in relatively rapid movement of research ideas to routine use. Historically, for example, the Berkeley and Los Angeles campuses of the University of California have produced important basic data. Many other projects under various sponsors have used these data to develop novel devices to improve the function of amputees. Both Mauch and Dupaco, for example, designed the patterns of drilled holes in their swing-phase control bushings from UC-BL data on knee torques, movements and timing to simulate normal gait. Conferences and workshops organized by committees of the National Research Council long have been effective in promoting such cooperation among laboratories supported by various sponsors, sometimes on an international level.

The conference reported in this issue brought together project leaders from both intramural and contractual laboratories. In a sense, this issue provides a snapshot of the status of numerous aspects of the VA prosthetics research program in mid-1974.

Perhaps the broadening of the prosthetics research program is the most striking impression for long term participants. Though work continues vigorously and with new approaches on such topics as locomotion, fitting of artificial limb sockets, or externally powered artificial arms, and the sensory aids program has long been active, there are now vigorous programs on relatively new areas. Selection of sites for amputation (or, indeed, prevention of amputation), wound healing of amputation stumps, and electrical stimulation for muscle activity, for feedback of sensation, or for accelerated bone repairs, are examples. Numerous types of equipment are being developed or evaluated for the spinal-cord-injured to use in the hospital, at home, on the job, and in transportation. Ingenious powered wheelchairs are under development

to provide not only new functions but also greater safety during travel in specially modified vans. New technical possibilities for serving the severely disabled and new legislation are factors in the broadening scope of the program.

In addition to the numerous obvious opportunities for fostering cooperation within traditional subdivisions, and for helping patients with multiple disabilities, the conference led to some new insights. One participant, who previously had been concerned with control of externally powered artificial arms and with novel techniques for measuring myoelectric signals, began to work with an audiologist on new instruments to manipulate speech signals for the hard-of-hearing. A clinical gait analyzer being developed for study of orthopedic impairments may also be useful for quantifying changes of gait pattern of a blind person as he is trained with a new electronic mobility aid. New materials for cosmetic restorations may also be useful for cosmetic covers of modular limb prostheses. The closed-circuit TV magnifiers which have been clinically evaluated for the partially sighted may also simplify reading tasks for certain quadriplegics. Knowledge of a critical survey of the literature on surgically implanted electrodes added to the background of a participant who was to review concepts for electrical stimulation of audition.

As a motion picture is a series of snapshots, so the successive issues of this Bulletin should provide in formal papers and in progress reports a view of a changing, complex, yet integrated program. The 10-year index in the last issue not only provides a guide to past positions but also, by dates and numbers of citations, provides some clues to historical trends. One may hope that future issues, like subsequent frames, will show steady, even accelerative, progress toward wider dissemination of better aids and techniques for some of the most seriously handicapped people in this country and the world.

WELCOMING ADDRESS

Clinton Compere, M.D.

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It is a great pleasure for me to be invited to welcome you not only to Chicago but also to this new building which houses the Rehabilitation Institute of Chicago. The building is an affiliated hospital, an integral part of the Northwestern University-McGaw Medical Center. Within this building we have expanded our own programs, under the supervision of the Department of Orthopedic Surgery, which have been struggling in less-than-adequate quarters in the old Rehabilitation Institute of Chicago building on Ohio Street. Most of you will want to go through this building with members of our staff.

The 17th floor of this building is entirely Northwestern University Prosthetic-Orthotic Education where we have now three major laboratories with programs for prosthetics and orthotics, classrooms, and plans for the future for the bachelor's courses. We now, for the first time, have totally adequate facilities for our current and future education programs. On the 14th floor, also under our supervision, is our research section. In this area two basic research sections, the Prosthetic Research Laboratory and the Rehabilitation Engineering Program, are combined. You will be most interested in seeing some of the work that Dr. Dudley Childress has been carrying on. Also, the Northwestern University Physical Therapy School occupies the fourth floor of this building. The rest of the building has research in rehabilitation medicine, four floors for patient care, the 12th floor for physical therapy and occupational therapy, the second floor for cafeterias, etc.

My own involvement in your programs, as many of you know, goes back to the beginning, in World War II when I was the first and really only Chief of the McGuire Amputation Center in Richmond, Virginia. Following this, after discharge from the Service, I thought I would get back into private practice, and not be too involved in amputations. Then my friend Paul Magnuson came along as Chief Medical Director of the VA and immediately put hooks on me to help organize the Regional Office Clinics, particularly the one here in Chicago. From that moment

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on, I have continued to be involved with the VA programs as well as Social and Rehabilitation Service and other HEW programs in prosthetics and orthotics. Paul Magnuson, as you know, had tremendous influence on changing the pattern of VA medical care and research, specifically in orthopedic and prosthetic-orthotic fields. Gus Thorndike worked in these programs with us in those days. He became involved in the Suction Socket Program as soon as he joined the VA in 1948, and we have been associated in various similar programs ever since.

Paul Magnuson was a professor of bone and joint surgery here at Northwestern before leaving to take the VA job, and he was personally responsible for the existence of the building we are sitting in right now. His influence on certain fields such as rehabilitation, particularly orthopedically oriented rehabilitation, has been tremendous. This 16th floor auditorium was named after him, and his portrait is in the lounge outside; also, a bas-relief plaque honoring him is hanging in the main floor lobby. We wanted to name the entire hospital after Magnuson, but he had expressly stated that he did not want that to happen, so it has not been done as yet. This really could and probably should be the Magnuson Rehabilitation Institute. He refused to let us dedicate it to him while he was alive, and his wife has held to this. She has since died and left us $1,000,000. His son still is very active with us on the Board.

All through the years, I have grown up working with many of the people that are in this room. In the very beginning were Howard Eberhart, Verne Inman, Gene Murphy, Chuck Radcliffe, and many others. Later, of course, Tony Staros and other people worked with us, as well as their associates, in these programs. As a natural progression and development, the VA Prosthetics Center was organized and has been working very effectively.

I worked with General Strong, who developed the Prosthetics Research Board and helped to coordinate originally many, many other activities. Then the coordination of the program passed to the Committee on Prosthetics Research and Development.

Also, in addition to these programs, I have been working with the VA and others in the spinal-cord-injury programs here in our own laboratory. The Prosthetic Research Laboratory is VA-sponsored and -financed. Our Rehabilitation Engineering Center is working in coordination with it, working very deeply in device development and in surgical implants. The panorama of our interest has greatly increased in the past 10 years.

This is a tremendous program in which you are participating. Each of you has your own interests and your own abilities that should be contributed to this meeting over the next few days.

One of the greatest supporters of all programs, of course, for many years has been Dr. Robert E. Stewart. He has been tremendous in his efforts in developing appropriate funding for many of our programs. Unfortunately, he has just reached the age where he was forced to become a consultant rather than continue full time. But most fortunate for us is the fact that we now have in the VA Central Office, in a little different type of setup, Dr. Thomas Radley, an orthopedic surgeon, who will carry on as chairman of this meeting. He is Deputy Director for Prosthetics in the Surgical Service and Acting Director, Prosthetics Research Service. Tom also is active in our Academy affairs. He works

with me on the Committee on Rehabilitation of the American Academy of Orthopedic Surgeons, and he is active as a member of the Committee on Government Legislation and Veterans Affairs of the Academy. He has been an Assistant Clinical Professor of Surgery at the University of Cincinnati, consultant to the VA and Chief of the Orthopedic Appliance Clinic Team there, and he is attending surgeon at the Washington, D.C., Veterans Administration Hospital. I can personally state that he has developed and maintained a real interest in our efforts and our programs, and we look forward to many years of pleasant association with Tom and the Central Office of the Veterans Administration. At this time I will turn the meeting over to Dr. Radley.

INTRODUCTORY REMARKS

Thomas J. Radley, M.D.

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I would like to make some general statements before we move on to the next speakers, because I have a feeling that the speakers are going to require more time than that allotted to them. The main purpose of this conference is to further prosthetic research and development for the disabled veterans.

Dr. Newcomb and his research group, including myself for prosthetics, in the past few days briefed the Chief Medical Director, Dr. Chase, concerning the VA research programs. I presented to him a copy of our latest Bulletin of Prosthetics Research indicating that this was considered to be the "Bible" of the prosthetics research world. I believe that he agreed with me in this concept.

I believe this type of gathering will give us the opportunity to meet, to exchange ideas, and to familiarize ourselves with other members in the prosthetics research field. If there are any administrative problems concerning the contracts, I shall refer you to Dr. Murphy. I assure you that I am very proud to be General Chairman of this conference, whose members are the leaders of prosthetic research throughout the world. If there is a theme for this conference, I would like to suggest "Positive Research Thinking, Positive Research Efforts, and (hopefully) Positive Research Results." Now we shall let Dr. Murphy, Director, Research Center for Prosthetics, introduce the remaining speakers. Thank you.

PREFACE

Eugene F. Murphy, Ph.D.

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It is a pleasure to see you all here. We have been planning a meeting of this type for a long time. It is perhaps particularly appropriate to meet in this very new building of the Rehabilitation Institute of Chicago and in the Magnuson Amphitheater. Professor Magnuson was a member of the original Committee on Prosthetic Devices, which arose out of a meeting in the next Northwestern University building, the Gothic-style Thorne Hall. A meeting there in January 1945 was supposed to standardize artificial limbs and to pick the best available artificial limbs and components. The meeting ended in chaos with nobody agreeing on the parts to include. The only uniform agreement was that there ought to be better limbs than those available. When Dr. Paul Klopsteg, who was a professor in the Technological Institute at Northwestern, reported this to the National Research Council as their delegate to the meeting, he was told to go ahead and develop a committee to improve artificial limbs. That led to the Committee on Prosthetic Devices, whose descendants are still here and still active. One of our first meetings of the research projects in the artificial limb program had been in the same Thorne Hall in January 1946. It is fascinating that we are now meeting in a much newer building of more modern architecture, and at a much higher elevation; I hope that this change is symbolic.

This conference, then, in a sense is a revival of some old meetings organized by NRC groups now represented by the Committee on Prosthetics Research and Development. It is fitting that Mr. Wilson, the Executive Director of CPRD, and a number of members of the staff are here with us.

I should like to introduce a couple of our own staff: Earl Lewis is Assistant Director of the Research Center for Prosthetics and has been deeply involved in the organization of this meeting. Mr. Howard Freiberger, Electronics Engineer on our staff, is Rapporteur.

The primary purpose of this meeting is to review the program as a whole in the light of the current state of the art, the VA's needs (which are not necessarily those of other groups), and the foreseeable trends,

especially trends that can be accelerated. We hope that we can encourage cooperation among the various projects and among the various disciplines involved in this very peculiar marginal field that Prosthetics and Sensory Aids represents.

For example, clinical gait analyzers could be useful not only for evaluating amputees and orthosis wearers, but also they would be useful with the blind rehabilitation sections in evaluating whether a blind person with a long cane has a good normal swinging gait or whether he walks with a typical blindism with his head back and reaching out with the tip of his toe to touch the ground to make sure that there *is* some ground ahead of him. Also, one can imagine using the electromyographic control systems, which have been used for the control of artificial arms as means of seeing whether a newly blind person is gripping the cane with unusual tightness, because he is scared stiff, or whether he is just holding it in a relaxed way. Similarly, one could study grip on the optical probe of a reading machine. One could see whether he is becoming fatigued in using it because of the intrinsic difficulty in learning the code, even from Harvey Lauer, or whether he is wasting muscle energy in gripping the probe with exceptional tightness. Thus, there are interrelationships between prosthetics and sensory aids that may not be completely obvious. But conversely, of course, we hope that some of the sensory aids work will help to provide sensory feedback in artificial limbs, for spinal-cord-injured patients, and so on. All of us can learn from each other and make intelligent contributions in discussions of each paper.

I would hope also that we can encourage transition from the research stage through design, development, evaluation, redevelopment, and ultimately into prosthetics education, such as Dr. Compere's school and the other two schools that are available at NYU and UCLA, and through the intramural seminars which Earl Lewis operates for the Veterans Administration, and, of course, through the papers in the literature in general, including the Bulletin of Prosthetics Research. Hence, designers could get drawings and early models, where indicated, into Mr. Staros' hands, so that he could go out on bid, get larger quantitites of models for broader evaluation, and eventually launch the device into the commercial market. Thus, developed from concepts of Ed Wagner, General Strong, and Ted Dennison, we have a systematic, orderly way of providing transition from early ideas through to a routinely used device, used not only in this country but throughout the world.

We welcome the cooperation between our program and the several other sponsored programs in the United States and are particularly happy that Joe Traub of the Rehabilitation Services Administration is here. There are also programs under the Office of Education and other agencies. It is important that all these groups work together.

We would like to encourage some focusing on early payoff devices and techniques at this meeting. You know there are many interesting, but fringe, ideas. All of us, I think, run the risk of becoming so diversified with numerous intriguing ideas that we never quite can pin down any one of them. It is important to try to focus on a few things, making sure to take them out while we are laying the ground work for other ideas.

Finally, we hope to improve the administrative side of the program. Mr. Thomas Conners of our office, a prosthetics representative, who is concerned particularly with budgeting aspects and reporting contractual matters, will be available. You may talk with him about that side. You will probably be hearing from him by correspondence and telephone. It is desirable to get persons acquainted. Finally, we hope that this meeting will encourage personal friendships, beyond the long standing friendships that some of us have had for a quarter of a century.

We are proud of the accomplishments of the program in the past. A collection of both items and techniques of fitting has reached wide use. We are also happy that we inadvertently made some improvements in economy. Mr. William H. Talley, in his editorial in the Bulletin of Prosthetics Research in 1968, demonstrated that he had saved over $28,000,000 in operating costs as a result of our spending $20,000,000 in research, so that's a worthwhile record. One can argue that we cannot afford not to have more research! We hope in similar ways better prostheses would lead to further true economies by making many handicapped people better adjusted to life and to the world. Thank you very much.

CURRENT STATE OF THE ART

Needs of the Veterans Administration

Anthony Staros

Moderator

Director, Veterans Administration Prosthetics Center
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It was believed by the conference organizers that I, as Director of the VA Prosthetics Center in New York, might constitute an appropriate individual to moderate a session to summarize the needs of our agency after first defining the current state of the art. It is probably well that somebody from our Center does this since as you may know, the VA Prosthetics Center is partly obligated to clinical care functions and partly to research, development, and evaluation. We have not only an outpatient program in prosthetics and orthotics but also now have a very heavy involvement in the spinal-cord-injury services of the Veterans Administration. We have very direct patient care responsibilities in the VA hospitals in our own metropolitan area and indirectly to the 171 hospitals of the VA system.

Our responsibilities are therefore to the entire Department of Medicine and Surgery of our agency. So it is perhaps best that we help moderate presentations about the current situation and the need based on our combined clinical and research roles in all the topics specified for this conference, especially prosthetics, orthotics, and spinal cord injury including mobility aids and environmental control systems. We, of course, have a lesser role in sensory aids research and clinical care but maintain a very direct interest in deployment of new equipment.

The multiple roles of the VAPC in research will be further defined by other members of our staff throughout the conference. We should remind you, however, that the VAPC has a special role to play in assisting each one of you in expediting tran 'tion of developed items from your laboratories into evaluation, testing, and eventually, clinical deployment and education. We have a special capability here which we make available in your service.

It is well that VA people, performing daily work with patients, come

before you and define VA problems. We cannot really depend on others—the universities, the academies and the like—to define for us, the VA, what our problems are. We must recognize our own problems. We then must be the ones who should come before researchers and define what these problems are so that they may in turn work toward delivering solutions.

The people on this panel are mostly in contact with VA patients. We should now like them to summarize what the current states of the art are and then specify for you the needs of the Veterans Administration.

SURGERY AS RELATED TO PROSTHETICS AND ORTHOTICS

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SURGERY AND PROSTHETICS

The single greatest obstacle to progress in amputation surgery has been the surgeon's lack of prosthetic knowledge. While a small number of surgeons throughout the years have become involved and, in fact, have made significant contributions to prosthetic improvements, the vast majority of amputations continue to be performed by surgeons uninformed in the area of prosthetic rehabilitation. This circumstance does not prevail in other areas of surgery where assistive mechanical devices used to restore function are generally well understood by the attending surgeon.

In the years since World War II, prosthetic engineering and design have improved dramatically. Of late, the prosthetist, as a member of the amputee team, turns hopefully to the surgeon, seeking more functional and physiological stumps. The accepted practice of so often fitting the prosthesis to a difficult, inadequate stump is questioned. This questioning is beneficially influencing surgeons to review and upgrade amputation techniques.

Immediate postsurgical prosthetic fitting has also influenced the amputation surgeon (1). Prosthetic replacement of basic lost function here becomes a part of the surgical procedure. The surgeon can now relate directly to prosthetic rehabilitation beginning at the time of surgical limb loss. The amputation now becomes reconstructive, for not only is the limb removed, but also a terminal, functional end-organ is created to accept and control the substitute part. This surgical approach dictates full conservation of stump tissues and relates direclty to prosthetic use. The amputation must respect the gentleness and technical finesse associated with reconstructive surgery of the hand or foot.

Coincident with these changing attitudes, the amputation has now moved into the main stream of surgical interest and research. The last authoritative atlas of amputations in English was published by Slocum

(2) in 1949. When one considers the vast volume of surgical literature, including monographs and textbooks since that date, amputations have commanded a small part of these communications. A review of recent literature, however, confirms the upswing in interest and progress in the field.

Amputation stumps in the lower limb, designed to use current prosthetic substitutes, totally contact the prosthetic socket and, whenever possible, provide some degree of end-bearing capacity. This includes diaphysial amputations as well as those through joints and metaphysical bone. Sectioned muscles are stabilized whenever possible at or near the end of the amputation site. Nerves are sectioned high and allowed to retract into soft tissues which cushion them from socket pressure. Bone is carefully contoured in a smooth manner to minimize skin sensitivity and soft tissue breakdown under pressure and shear stress. Tibial-fibular synostosis will improve stump strength and stability in certain specialized below-knee amputations. Skin management and scar placement will be dictated by the physical circumstances present, specifically, the nature of the skin and its blood supply. The goal is a nonadherent and nontender scar. Long accepted and relatively dictatorial skin flap and scar placement directives have to a large degree been abandoned or modified. As the surgeon amputates, he continually thinks of the resulting stump-socket interface of the prosthetic replacement.

Specifically in the lower limbs, the Syme (Fig. 1) and below-knee (Fig. 2) levels are by far the most statistically important. Both forefoot and Syme amputations are being performed in increasing numbers. Two-stage techniques, particularly at the Syme level, are gaining increasing favor, especially in the diabetic.

Most below-knee amputations now utilize a longer posterior skin and fascial flap. The advantages of this type of amputation have been

FIGURE 1.—Postoperative Syme amputation demonstrating proper contour and shape.

FIGURE 2.—Cylindrical, partial end-bearing and muscle stabilized below-knee amputation stump suitable for modern prosthetic fitting.

pointed out. At knee-disarticulation level, recent useful modifications include a minimal removal of condyles with the patella (Fig. 3) and with resuture of the quadriceps mechanism. The center of axis of motion of the knee joint can then be placed in an essentially normal position as related to the opposite knee, allowing the use of intrinsic knee mechanisms in the prosthesis (Fig. 4).
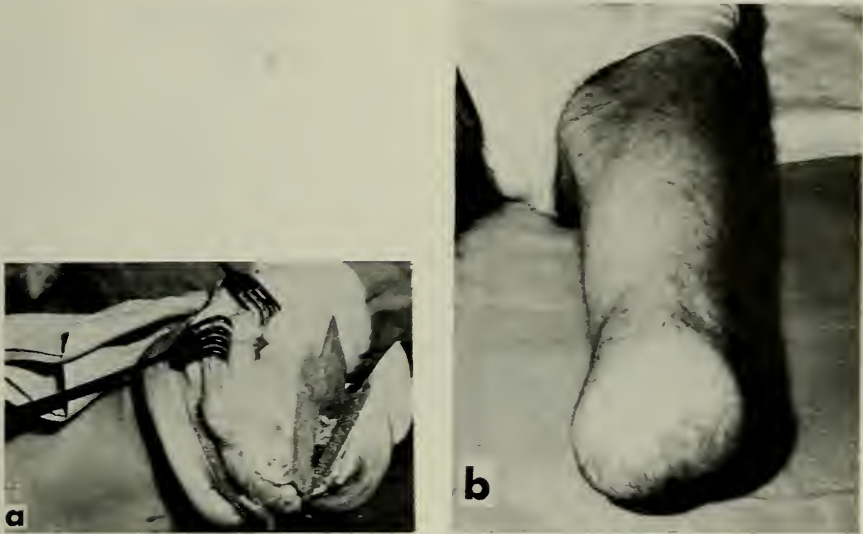
FIGURE 3.—a. Twenty-one-year-old male with modified PRS low transcondylar knee disarticulation illustrating level of amputation through the knee joint. b. Healed amputation with end-bearing suspension capability of the stump.

FIGURE 4.—The center of axis of prosthetic knee movement can now be approximated to the opposite leg.

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Through-thigh amputations require full attention to muscle stabilization since most above-knee prostheses are no longer suspended by a pelvic belt with hinge, and stump muscle power and bulk are critical to full function potential (Fig. 5). Hip disarticulation is an increasingly acceptable level of functional limb ablation because of the advances in prosthetic technology (Fig. 6).
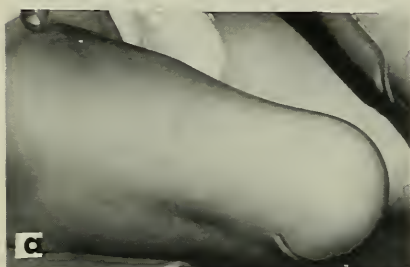
FIGURE 5.—a. Stump of 13-year-old male with amputation for osteogenic sarcoma of the proximal tibia. b. The stump is functionally suited to utilize modern prosthetic units.

FIGURE 6.—Fifteen-year-old female with osteosarcoma of the femur; this illustrates the amputation site (hip disarticulation) suitable for maximum function with current prosthesis.

New surgical innovations are being made with regard to the placement of the scar in the hemipelvectomy procedure and the design of the amputation area suitable for limb fitting (Fig. 7).

FIGURE 7.—Fifty-six-year-old male with hemipelvectomy from fibrosarcoma. This illustrates the placing of the scar and the design of the amputation area suitable for limb fitting.

In the upper limb, maximum stump length is preserved, muscle stabilization is routine as surgical circumstances permit, and scar placement follows the general rules of plastic surgery. Wide availability of externally powered upper-limb prostheses directs the surgeon to retain myoelectric signal sources within the stump. Appropriate surgery will also facilitate the use of displacement and other pressure sensor afferent sources in many patients.

We have recently been studying the muscle suspension capabilities of both upper- and lower-limb stumps. Voluntary and involuntary muscle activity within these stumps can substantially aid limb suspension. Retention of muscle size, shape, and power, together with complementary socket design, requires prosthetic-oriented surgery.

SURGERY AND ORTHOTICS

The orthopedic surgeon has for decades used a wide variety of operations to eliminate the use of orthoses or to limit their scope and need. This surgery developed as a result of the thousands of patients crippled by poliomyelitis, tuberculosis, osteomyelitis, septic arthritis,
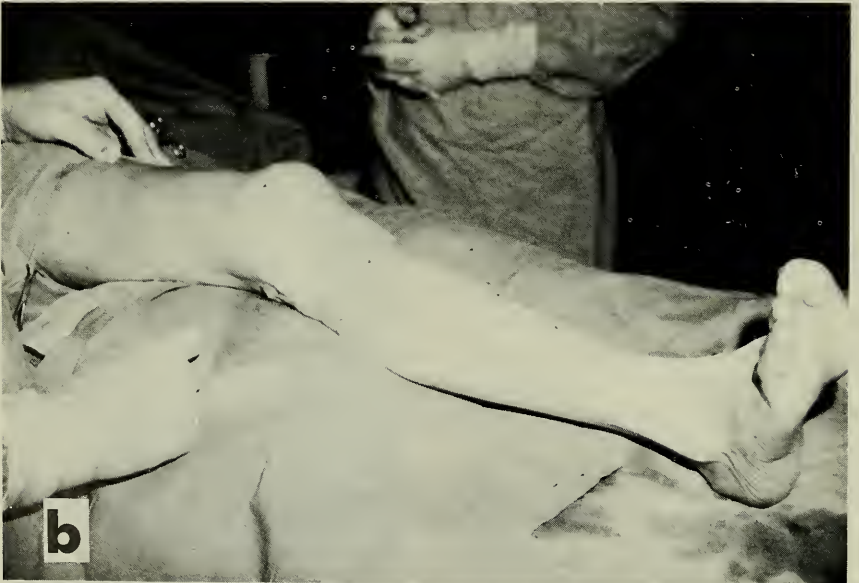
FIGURE 8.—a. Photo depicts bipolar electrode placement around the common peroneal nerve at knee level for neuromuscular assist device in a 70-year-old male with CVA. b. Stimulation at surgery indicating receiver site and response of dorsiflexors of the ankle and foot.

trauma, tumors, and congenital anomalies. Joint arthrodesis, osteotomies, tendon transfers, tenodesis, limb discrepancy correction, and other deformity correcting and motion restraining surgery made up the major volume of the older orthopedic surgeons' work. Many of these crippling diseases have largely disappeared. Nonetheless, our rich heritage of experience is still applicable to currently encountered functional limb and spine deficits requiring orthoses.

More recently, surgical techniques have been developed to utilize sources of external power, i.e., electricity, compressed gas, spring mechanisms, etc., to facilitate orthotic substitution or to eliminate the use of orthoses. An example would be the neuromuscular assist electrodes placed on the peroneal nerve where brain damage and/or upper motor neuron involvement results in drop foot (Fig. 8). Further reinforcement surgery of this type is in the future.

CONCLUSIONS

Amputation surgery as never before is being directed toward prosthetic rehabilitation. This trend can be expected to continue and accelerate. Most surgeons performing amputations are unaware of the bioengineering implications incident to the surgery itself. Education at the clinical level needs top priority. Prosthetic and orthotic rehabilitation could be greatly improved if present improved surgical techniques were more widely used. In no field of surgery is bioengineering more relevant; the much discussed man-machine interface joins here. Its union will be successful only to the degree that the surgeon recognizes his role and responsibility.

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PROSTHETICS

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When the Veterans Administration launched its first research programs to help elevate prosthetics from a craft to an art-science, appliances were generally hand carved of wood or made with adjustable leather sockets attached. Joints at the ankle, knee, and hip consisted mostly of single pivot metal joints poorly designed and poorly aligned. The suspension systems were crude strap and belt affairs which offered poor control of the prosthesis. The functional controls available at the various joint levels were confined essentially to those necessary to limit the range of motion. No standard methods for fitting or alignment of prostheses were in existence. Each prosthetist used his own methods which were carefully guarded secrets. Very little literature was available to guide or train new personnel. The field was totally ignorant of the biomechanical aspects of prosthetics or the physiological impact of their services upon the patient.

Few means were available for purchase of appliances through third party sources, and no funds were available for research or education in the field.

During the past 30 years, much has occurred in the way of progress due to the early government subsidies which were made available for the development of rationales for design and fitting of sockets and the alignment of prostheses. These developments, followed closely by the design and development of the suction socket for above-knee amputees and the recognition of the biomechanics involved in fitting and alignment, launched an avalanche of developments which influenced the redesign of prostheses at all levels. These changes were enhanced through the use of new materials (primarily plastics) and sophisticated componentry. Following the introduction of immediate postsurgical and early-fitting concepts, total contact and self-suspended sockets became the standard. Replacements for anatomical knee joint functions lost through amputation surgery were improved by many sophisticated knee mechanisms which provided both stance and swing controls. Functional standards for components, hardware, and softwear were

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established. Prefabrication of parts and assemblies followed. Fitting and alignment tools were developed to satisfy the new demands of the interim prosthesis concepts and temporary fittings used as diagnostic tools and training devices. The clinic team concept of patient care with all disciplines involved had become a routine procedure. All persons involved were now fully trained and had ready access to up-to-date information through the various technical publications and university training centers.

Highly skilled professionals in medicine, engineering, and education were now interested in prosthetics rehabilitation. They found the field challenging and their contributions gratifying. Although these changes have favorably influenced prosthetic functions essential for acceptable mobility, they leave a great deal to be desired from the patient's point of view in terms of security, versatility, weight, cosmesis, and reliability. Various innovations have been applied to the prosthetic foot and hip to simplify their functional design. However, the net result to the stance security and function of the overall prosthesis remains insufficient. There is no doubt that the level of utility and patient acceptance demonstrated with these appliances is considerably higher in general than that with patients wearing upper-limb prostheses. However, this could be motivated by a strong desire to be mobile and the relatively low level of functional demands necessary to ambulate. At any rate, even in the presence of this seemingly high level of achievement, the following further improvements are desperately needed: 1. A voluntary knee control system is required which will accommodate the wide range of stance and swing functions. The systems should be lighter than the knee units now available and should be smaller to accommodate better cosmesis. 2. A durable prosthetic skin is required whose physical characteristics will not conflict with the functions of the underlying components. The single largest drawback of endo-skeletal prosthetic systems has been the lack of an acceptable cosmetic finish. 3. By design, prosthetic feet are not generally intended for use on one specific prosthesis nor are they sufficiently adjustable to meet the needs encountered in all situations; therefore, it is desirable to develop adjustable prosthetic feet with a greater functional capability and better cosmesis. 4. We must continue to seek better socket interface materials and techniques which will be more compatible with body dynamics.

Although upper- and lower-limb prosthetics traditionally have been considered within the province of all prosthetists, there has existed a wide separation of interests among us which has caused an inequity in the pursuit of advancement for the development of these two disciplines. There is no doubt that, of the two, lower-limb prosthetics has continually enjoyed the greater degree of patient acceptance and utility. In spite of the big push during the 1950's to update upper-limb

prosthetics with the most modern fabrication methods, utilizing new plastic materials and incorporating more sophisticated controls, the level of acceptance and relative utility of upper-limb prostheses, even in the face of these advances, has never approached the record obtained in lower-limb prosthetics.

Prior to this time, upper-limb prostheses generally used body power to position the terminal device for operation and to open it against some form of elastic resistance. Because of the power transmission systems and the harness designs used, the functional level-to-force ratios were poor. The terminal devices were typically spring-loaded hooks of many configurations, each adapted to a special function. These appliances were considered tools rather than hand replacements. To obtain a greater level of utility, to this day we often advocate the use of "hooks" in preference to the prosthetic hand. In fact, there is now a drive on to develop an externally powered "hook."

The development of the APRL hand undoubtedly signaled our first serious efforts to promote hand function in prosthetics. It also constituted the first voluntary closing device of any consequence. This functional mode is still employed in the electric and myoelectric hands of today. Although these terminals devices provide better cosmesis, their level of function, their reliability, and their weight are still subjects of great concern to those patients who use them. Perhaps during the transition in our application of external power, from the early use of gas-powered systems to the modern electric-powered systems, we have unwittingly perpetuated the traditional problems which have assailed us from the beginning.

In reviewing the current state of the art it becomes evident that: 1. Emphasis must be placed upon more sophisticated functions controlling both the positioning of the terminal device and its operation. Reliable proportional control systems coupled with feedback and coordinated simultaneous motions are urgently needed. 2. More efficient components in the electrical system are required to further reduce weight and noise. 3. Better quality, product reliability, and functional reliability must be achieved. 4. Combinations of power sources and control systems must be exploited by establishing standards which make interchangeability of components possible. 5. Less restricting and more versatile suspension and control systems should be studied which might include changeable active and inactive modes. 6. Efforts should be given to develop a new outlook on the indoctrination, evaluation, and training of patients in light of the new socio-psychological climate in which we live.

Our patients are no longer sympathetic to the assumed indifference of the developers or crushed by the implied lack of technical expertise. They are no longer content to accept our inability to provide adequate

restoration of missing function. We are challenged today as never before. Scatter-gun techniques of development cannot begin to meet this vital duty. Only through well organized coordinated effort specifically directed at the recognized problems can we begin to satisfy this commitment.

ORTHOTICS

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Prior to World War II orthotics was essentially a metal and leather craft which appeared to have reached the limits of its development with the materials and expertise employed. Following World War II the clinical engineer, the physiologist, and the rehabilitation specialist entered the field, and the bracemaker was metamorphosed into an orthotist. Their combined talents were directed at moving away from the static immobilization types of devices to the active, functional orthoses that all centers are now concentrating upon developing. The introduction of plastics and external power was an important landmark in this revolutionary trend, a trend guided by the highly trained specialists newly involved in orthotics. In 1956, Thorndike, Murphy, and Staros (1) proposed suggestions for the application of engineering principles to the future design of orthoses, and recommended such improvements as the prefabrication of orthotic components and higher orders of quality control by manufacturers.

It is understandable that the simpler problems would be approached first. The most varied and greatest efforts have been concentrated on ankle-foot orthoses, an area where the need for sophistication contrasts with the requirements for functional hand orthoses.

Ankle/Foot Orthoses (AFO) research has resulted in the production of the Teufel (2) polyethylene and the polypropylene AFO's (Fig. 1), as well as the commercially available TIRR and Snelson Orthoses, the VA Prosthetics Center Shoe-Clasp Orthosis developed by McIlmurray and Greenbaum (Fig. 2) (3), the Lehneis Spiral Orthosis (4) (Fig. 3), and the Ljubljana functional electrical stimulator (FES) (Fig. 4). Liberson (5), who stimulated the research on FES by his original work, continues to retain his interest in this area and is at present working to perfect an equino-varus control orthosis which will combine muscle and nerve stimulation in a balanced manner to more accurately achieve neutral foot dorsiflexion for the hemiplegic. New York University (6) has advo-

cated anatomically aligned ankle joints for the double-bar orthosis and has improved the cosmesis of their orthosis by employing a polypropylene shoe insert attached to metal uprights.

FIGURE 1

FIGURE 2

FIGURE 3
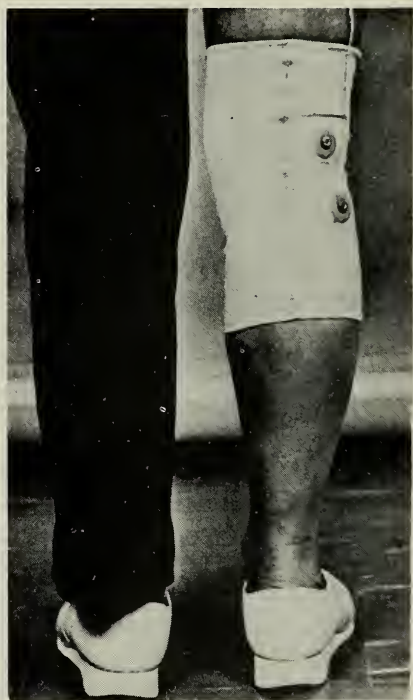
FIGURE 4

The lightness and cosmesis of polypropylene logically led to the fabrication of Knee/Ankle/Foot Orthoses (KAFO's), from this material by the addition of a thigh cuff and polypropylene joints to the AFO (Fig. 5).
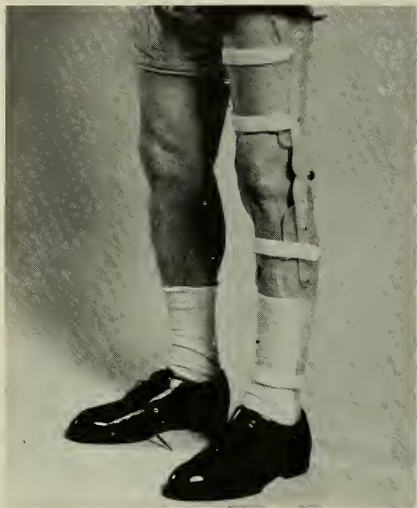
FIGURE 5

Similarly, the need for a lightweight lower-limb orthosis produced the Ortazur, a French product, and an American version called the Ortho-Walk (Fig. 6). The Ortazur was highly successful in the treatment of children with congenitally fragile bones (osteogenesis imperfecta). It is also being experimentally tested for paraplegics. These Knee/Ankle/Foot Orthoses (KAFO's), Ortazur A and Ortho-Walk (Fig. 7), would appear to have limited usefulness. The Hip/Knee/Ankle/Foot Orthosis (HKAFO) (Ortazur B) may have a wider application enabling midthoracic level paraplegics to stand and exercise. There are still some problems: the patient cannot sit comfortably without unzipping the device (Fig. 7); the patient must deflate each time he wishes to sit and inflate whenever he wishes to stand; and perspiration within the orthosis is still a factor with some patients. The area of application for the Ortazur or Ortho-Walk will be more clearly defined with further experience.

Polypropylene KO's have been developed by Dixon and Palumbo (7), employing a suprapatellar suspension strap modeled after the PTB strap.

The UC-BL foot orthosis (8) for flexible pes valgoplanus has also been fabricated of the versatile polypropylene. The foot deformity is corrected during casting, and it is the purpose of this orthosis to attempt to maintain the corrected position on weight-bearing (Fig. 8).

The PTB orthosis for below-knee instability or weight-bearing pain has been secure in its acceptance for many years (Fig. 9). This was the

FIGURE 6

FIGURE 7

FIGURE 8

first significant application of prosthetic principles to orthotics. Another important application of these principles was that of Murphy (1) who demonstrated the usefulness of the SACH heel and rocker bar when employed with a solid ankle orthosis. The quadrilateral socket orthosis (Fig. 10) provides partial unweighting of the hip and more distal structures. Both this approach and that of its forerunner, the PTB orthosis, were the antecedents of fracture bracing techniques. The development of orthoses for the upper limb has been slower and more difficult than the development of those for the lower limb. The problems of positioning the jointed upper limb in space, targeting the paralytic hand, and then providing that hand with useful function are extremely complex and require multiple controls. The orthosis developed at Rancho Los Amigos Hospital (9) for the quadriplegic illustrates an heroic attempt to provide some function for this type of total disability. The Rancho orthosis is a tongue-switch controlled remote manipulator (Fig. 11). Schmeisser and Seamone,[a] at Johns Hopkins, are experimentally approaching this same problem by attaching a remote manipulator to a

[a] See "Status of the Johns Hopkins Research Program on upper-limb Prosthesis-Orthosis Power and Control Systems," by Seamone and Schmeisser, Jr., appearing elsewhere in this issue of the Bulletin.

wheelchair arm and using other control systems such as an accelerometer, temporal muscle myoelectric control, and vibratory controls. They have also been testing a cable device to accomplish elbow flexion. Current, and promising, research is directed at the production of clinically useful voice control devices.

FIGURE 9

FIGURE 10

The VA Prosthetics Center is experimentally fitting an electrically operated orthotic elbow and hand system to a patient with a flail upper limb secondary to total brachial plexus avulsion (Fig. 12).

The Engen wrist driven splint (10) and, in the absence of voluntary control, the use of the McKibben muscle or myoelectric control are familiar approaches to provision of function to the paralyzed hand (Fig. 13, 14 and 15).

In the area of spinal orthotics, the newer developments have been limited. The Sterno-Occipital-Mandibular-Immobilizer cervical orthosis of Nitschke (11) is simply applied without moving the patient (Fig. 16). The prefabricated VA Prosthetics Center lumbosacral orthosis designed by Rubin and Greenbaum (12, 13) adds a "Milwaukee brace" type of stimulus to withdrawal to a contoured plastic orthosis and provides the patient with a socket into which to rest the portion of the trunk super-incumbent to the lumbar spine (Fig. 17). Morris' (14) UC-BL lumbosacral orthosis is a plastic laminate flexion jacket with a pneumatic abdominal pressure pad. John Hall [b] is involved with the development of a modular Milwaukee brace, and Staros has proposed that the VA

Prosthetics Center explore the possibility of fabricating a bilevel scoliosis orthosis based on a modular Milwaukee plus the VA Prosthetics Center lumbosacral orthosis.
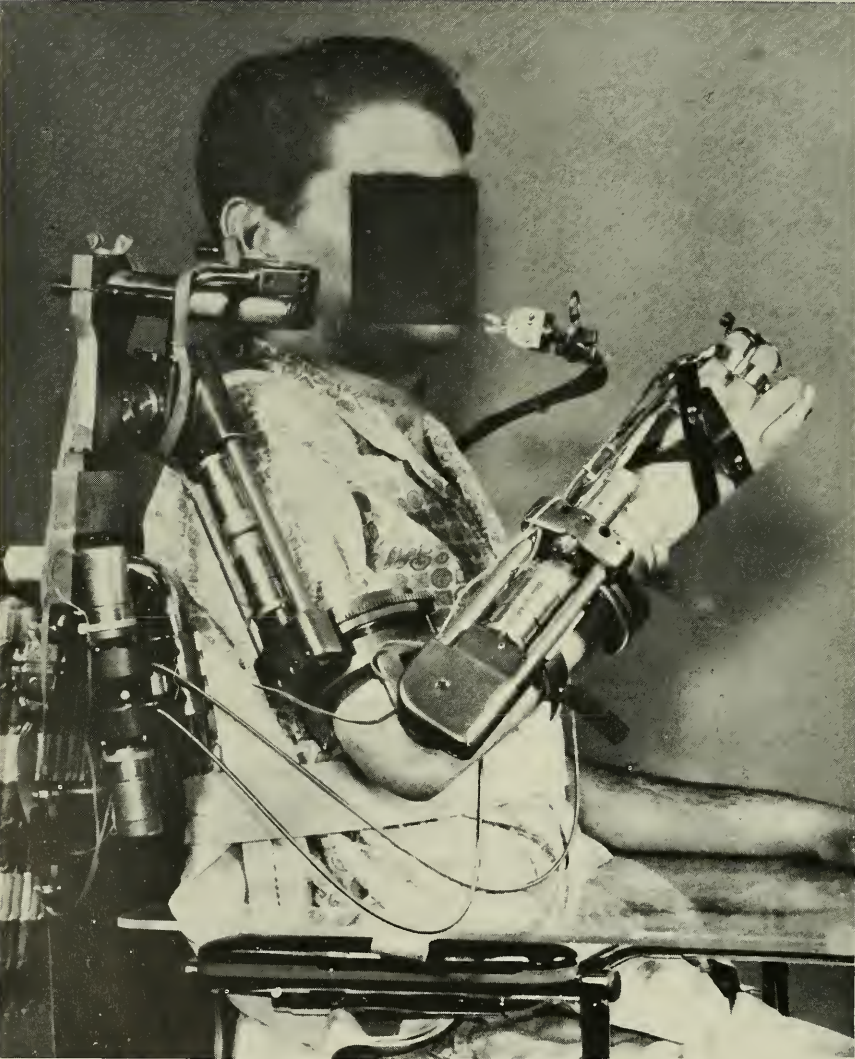
FIGURE 11
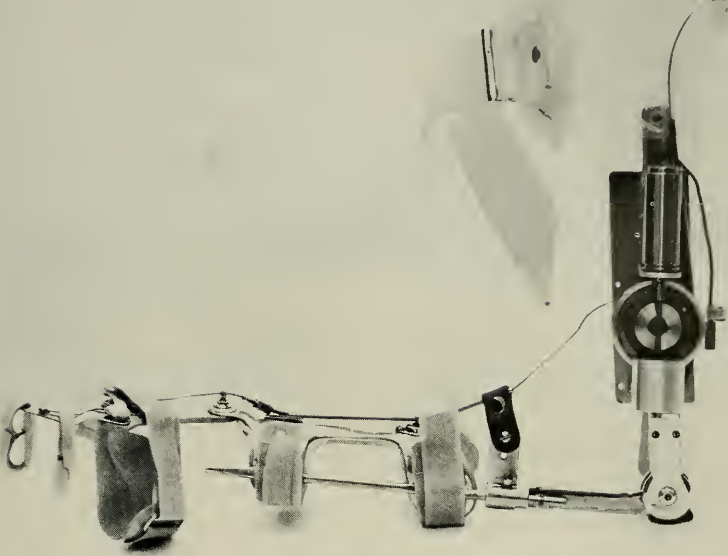
FIGURE 12
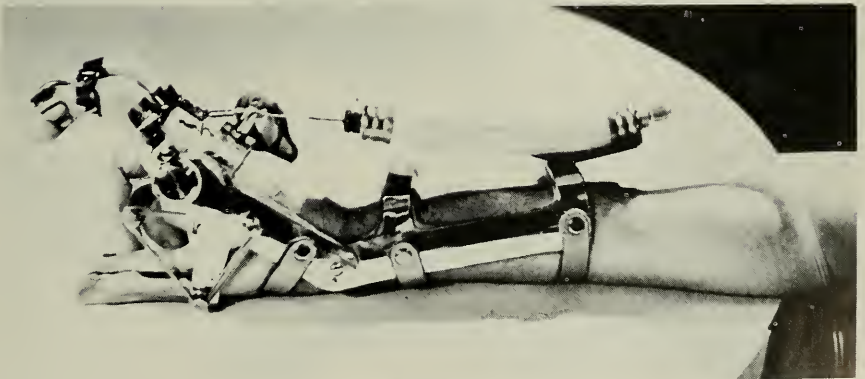
FIGURE 13
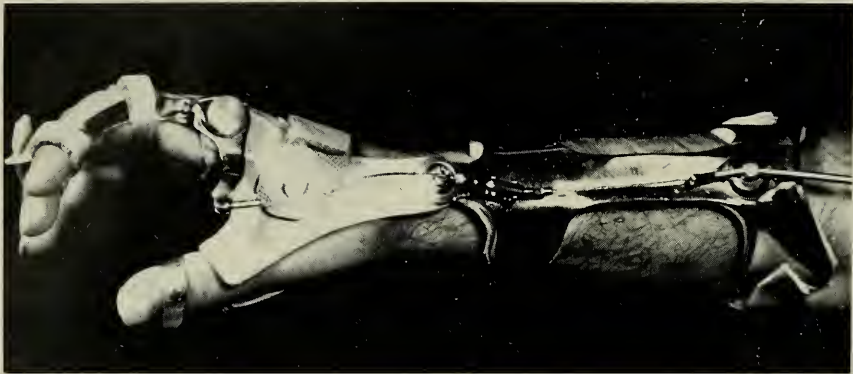
FIGURE 14

FIGURE 15

FIGURE 16
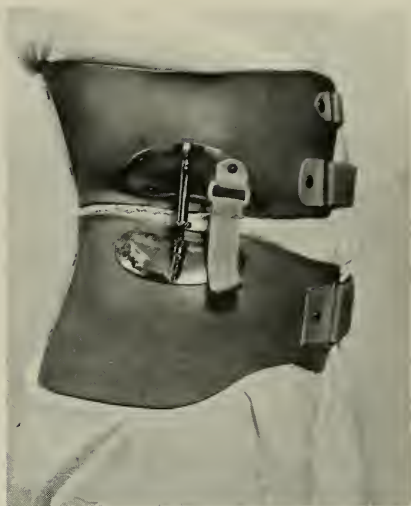
FIGURE 17

The needs for future development are most apparent in the upperlimb area, and, most particularly, for the quadriplegic, the hemiplegic, and the patients with peripheral nerve upper-limb problems. Experimental work is being done in the area of sensory feedback for the amputee where peripheral nerves are present in the stump; but the need is just as great in the case of the paralytic with sensory impairment, and an effort should be made to reach a practical solution to this problem. There is need for a simple, functional, inexpensive orthosis for the quadriplegic upperlimb—one that will not make the patient feel robotized. Perhaps the solution will be in the experimental efforts being made by Liberson and Dixon to utilize FES in this respect.

The spastic upperlimb of the hemiplegic is a constant reminder of an almost neglected area of research. Conventional orthoses are of little help. Perhaps the FES approach may help to improve this difficult situation. Certainly, more should be done for these patients than is being done.

Although the area of need is greatest in the upperlimb, this is not to suggest that all lower-limb and spinal problems have been solved; for example, adequate orthoses are not available in many areas. For the mid-thoracic paraplegic who does not have pelvic control, there is no truly adequate orthosis for immobilization of the dorsal spine, or one for providing the patient with hip stability in the presence of paralyzed hip-control musculature.

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THE CLINICAL ENGINEER AND THE
SPINAL-CORD-INJURED PERSON

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I would like to discuss with you the role of the clinical engineer in the care of the person with spinal cord injury. I use the word "person" rather than "patient" because the former helps us maintain a proper focus on the meaningful relationship that should be established between the engineer and the individual who has suffered a spinal cord injury. Of course, in our system of care, we must use the label of "patient" for administrative reasons. But the "person" with spinal cord injury knows only a daily life in which there is severe, overwhelming physical disability of paralysis of the legs (paraplegia) or paralysis of the arms and legs (quadriplegia).

Those we care for in the Veterans Administration are all adults. They have known in the past what it was like to be healthy, physically active, and independent. Then suddenly one day they found themselves unable to move their arms or legs. In over two-thirds of the instances, no other associated injuries to head, chest, abdomen, or fractures of the limbs were incurred. Due to an accident of some sort, instantly they found they could not move their arms or legs, and the skin of the involved part was without sensation. Not even a pin prick could be felt. The arms and legs appear normal and show no signs of injury, yet the person cannot voluntarily move them. The limbs simply will not respond. The trauma to the spinal cord has interrupted the transmission of messages from the brain to the muscles of the limbs.

Some persons with spinal cord injury are fortunate in that the paralysis disappears partially or completely, permitting physical independence. However, most persons who are completely paralyzed immediately after injury, and who do not recover any function within a few hours or days, remain permanently paralyzed. This person must therefore learn how to plan a lifestyle of coping with this physical and functional disability. The clinical engineer, by getting to know the spinal-cord-injured person and having some appreciation of his goals.

can help him help himself to greater functional independence and a meaningful life.

In the United States today there are estimated to be from 100,000 to 200,000 persons with spinal cord injury. The annual incidence is thought to be approximately 10,000 to 20,000 cases. Spinal cord injuries result from developmental defects of the spine and spinal cord in children, various diseases, and a significant number from traumatic injury to the spinal cord, resulting in quadriplegia or paraplegia.

Beginning in the 1940's, during World War II, the VA began organizing special bed sections in selected hospitals to care for these spinal-cord-injured persons when hospital care became necessary. At the present time, there are 16 such spinal-cord-injury treatment centers in various parts of the country. Their size ranges from 20 beds to 204 beds, with the Long Beach VAH as the largest spinal-cord-injury service in the world. The Veterans Administration has now on its roll approximately 20,000 veterans with spinal cord injury.

At the time of World War I, 90 percent of the spinal-cord-injured patients died within the first few years after injury. After World War II, with the development of antibiotics to combat infection, over 90 percent lived for many years after injury. At present, the patient who survives to reach a hospital after sustaining injury has a life expectancy almost equal to that of the noninjured.

The highest incidence of spinal cord injury occurs in young males between the ages of 15 to 35 years. These young men have a long lifetime ahead of them. Roughly, about 50 percent are paraplegics and 50 percent are quadriplegics. However, due to the fact that the quadriplegics are more severely handicapped and have more difficult complications, the quadriplegics quite often outnumber the paraplegics in the hospital setting. There is also an actual increase in the number of quadriplegic patients because more high level quadriplegics, i.e., injury at the fourth cervical segment and above (C1 through C4), are surviving the injury due to improved methods of medical care and transport immediately after injury. These high level quadriplegics have a more pronounced disability. They are able to use their head and neck, but have no voluntary movement of any muscles of the shoulders, arms, hands, trunk, or legs.

We usually expect the paraplegic (paralyzed from the waist down) to become virtually independent in activities of daily living. He can move about quite fully by wheelchair and automobile without any assistance. Many such persons travel about this country each day by car and plane unaccompanied by any assistant.

The quadriplegic, however, faces a much greater challenge. In addition to the loss of some or all voluntary movement of the arms and hands, there is paralysis of the chest and back muscles, causing impair-

ment in breathing and difficulty in maintaining body balance, even in wheelchair stability.

Although, the quadriplegic appears to be in need of appreciable assistance, it has been estimated that 80 to 90 percent of all spinal-cord-injured patients can be discharged from the hospital, including quadriplegics. Moreover, even with the present state of the art, at least 50 to 60 percent of spinal-cord-injured persons can be employed in some gainful occupation, and many additional persons can develop significant avocational activities. The thrust of these statements should encourage expectancy in the spinal-cord-injured patient and family that there can be a discharge from the hospital to a meaningful life in the community. The clinical engineer can significantly assist this progressive course of rehabilitation all along the way, and ultimately into the home and the community.

The clinical engineer must be continually sensitive to the fact that most of the persons with spinal cord injury have not suffered any brain damage. Nor is there any significant change in the personality of the individual. Therefore, the most significant resource available to the patient is still present—his mind. The person with spinal cord injury is usually mentally alert and often has strong will power. Our task and responsibility is to utilize this cerebral talent together with whatever motor and sensory capabilities remain to bring about a satisfactory restoration to community living, if at all possible. We assist the patient to develop an expertise which enables this satisfactory living pattern.

The clinical engineer should be an integral part of the treatment team from the initial phase of treatment through the rehabilitation phase, and into the outplacement period. Further, this ongoing contact should be maintained throughout the life of the individual. The Veterans Administration assumes that it has an obligation to the spinal-cord-injured veteran throughout his lifetime, not only in times of emergency, but also in such a way as to prevent the need for hospital care. Further assistance is also extended this person to help him achieve his selected goals.

During the past few years, the Spinal Cord Injury Service of the Veterans Administration has initiated a progam of home care after the patient is discharged from the hospital, which has proven successful. Predischarge evaluation and planning for the selected patients enable a multidisciplinary team to effectively outplace and care for patients who otherwise would not be considered suitable for outplacement away from the hospital premises. Unexpectedly, approximately 50 percent of those outplaced have been quadriplegics, many with severe physical disability, and including some who had been hospitalized for 10 to 15 years and had been previously considered noncandidates for outplacement.

We have had the clinical engineer visit the home of the spinal-cord-injured person to assist in devising ways to make life worth living. The

engineer should also assist in devising a suitable interface between the spinal-cord-injured person and the environment by following the trail from home to school, or job, or recreation.

Just 30 years ago, during World War II, spinal-cord-injured persons received their first expectation of surviving the trauma. This fresh hope resulted from the newly introduced initial antibiotic drugs and better systems of care. However, in the intervening years, little organized help was given to the spinal-cord-injured person in terms of his expecting to regain independence and return to a full life in the community. Meanwhile, technology has continued to make large, rapid strides. Today, we are still receiving some technological fallout from the "moon" program. The clinical engineer can and should assist in applying some of this available technology to the needs of the person with spinal cord injury. Perhaps one day a paraplegic might also travel to the moon. After all, in a gravity-free environment, much that is considered physical disability on earth disappears.

TRENDS IN NONLICENSED MOBILITY AIDS

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The scope of nonlicensed vehicles includes electrically powered wheelchairs, golf-cart-type vehicles, a variety of multifunctional devices, and some gasoline-engine-powered vehicles. Until several years ago, the standard nonlicensed powered vehicle was the Everest & Jennings "34" Power Drive Wheelchair (Fig. 1). This unit has been directed to institutions and general indoor environments where it has enjoyed considerable success. Several offshoots of the basic Power Drive include the Motorette, the Rolls Electric Wheelchair, and the Everest & Jennings "33" Power Drive. All of these powered wheelchairs, including the "34" Power Drive, are normally operated by hand-manipulated joy sticks. The Everest & Jennings "34" Power Drive and the Rolls Electric Wheelchair are essentially equivalent in performance. The former incorporates a belt drive while the latter uses a direct friction drive. The Motorette (Fig. 2) is rather novel in that it is an "add-on" assembly, capable of converting virtually any conventional wheelchair into a powered unit. Both the Motorette and the Everest & Jennings "33" Power Drive incorporate proportional control joy sticks, exemplary of an introduction of electronics into physical rehabilitation. The more severe spinal-cord-injured quadriplegic and similarly paralyzed individual are generally unable to use manual joy-stick controls. Several years ago, Everest & Jennings introduced a chin-controlled joy stick (Fig. 3). The aerospace industry generated considerable initial excitement with the Sight Switch (Fig. 4), that depended upon movement of both eye balls to effect wheelchair control via special optical switches. Breath controls have appeared in some clinics and other techniques are being investigated.

It is interesting to note that the two common types of wheelchair drives, including belt and direct friction drives, have both been under attack from time to time for a variety of reasons. For instance, the direct friction drive generally exhibits excessive tire wear while the belt drive usually requires frequent adjustment and is difficult to push when

FIGURE 1.—Everest & Jennings "34" Power Drive.

malfunction occurs. In view of these and other apparent problems, an effort has been underway to develop a "powered wheel," a device that incorporates one or more motors within a special wheel assembly (Fig. 5). Such a unit is now available in the United Kingdom through Dudley Controls, Limited. Here in the United States, Gar Wood Enterprises, of Miami, Florida, is developing a similar system.

For many years, a demand has existed for the development of a truly portable, foldable, electrically powered wheelchair. The conventional powered wheelchairs are neither portable nor foldable, in a practical
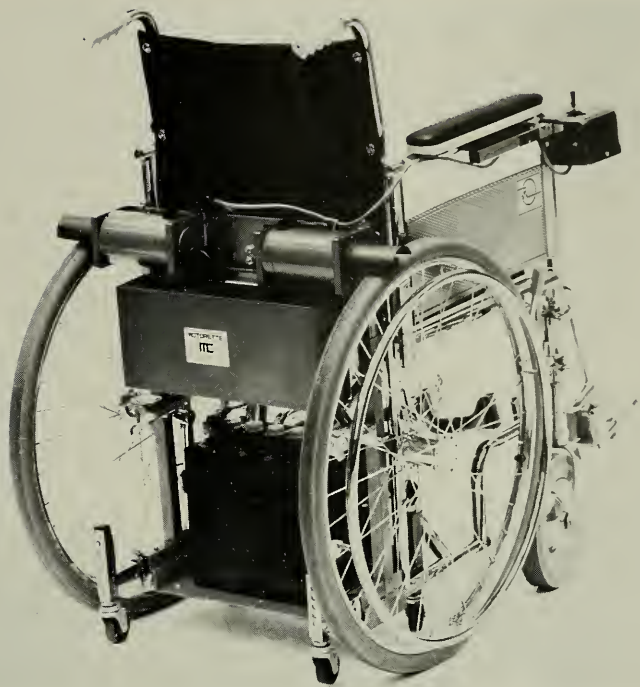
FIGURE 2.—Motorette.

sense, since the wheelchair user is unable to independently handle the one (or two) battery(s), which serves as power source, or the wheelchair, which generally incorporates a heavy duty construction and the burden of additional weight of both motors. Usually, more than one person is required to disassemble the chair and to put it into an automobile trunk for transportation. Consequently, we have seen one or two attempts for the development of a small power unit. A response to this demand, is the A-BEC Electric Wheelchair (Fig. 6), available from the United Kingdom. It is apparent that while the unit offers lightweight construction, it fails to match the characteristics of a conventional wheelchair configuration and structure for many wheelchair users. Also, it should be noted that the reduced battery and motor size necessarily result in reduced performance which seems contrary to the needs of many of today's veterans.

Many VA patients refuse to be confined to the immediate physical environment of the home or hospital. The younger spinal-cord-injury-type patient is frequently motivated to achieve a relatively high level of independence. Many of these individuals have returned to school in order to improve their economic and social potential. Consequently, on the university campus and in typical nonurban areas, these individuals
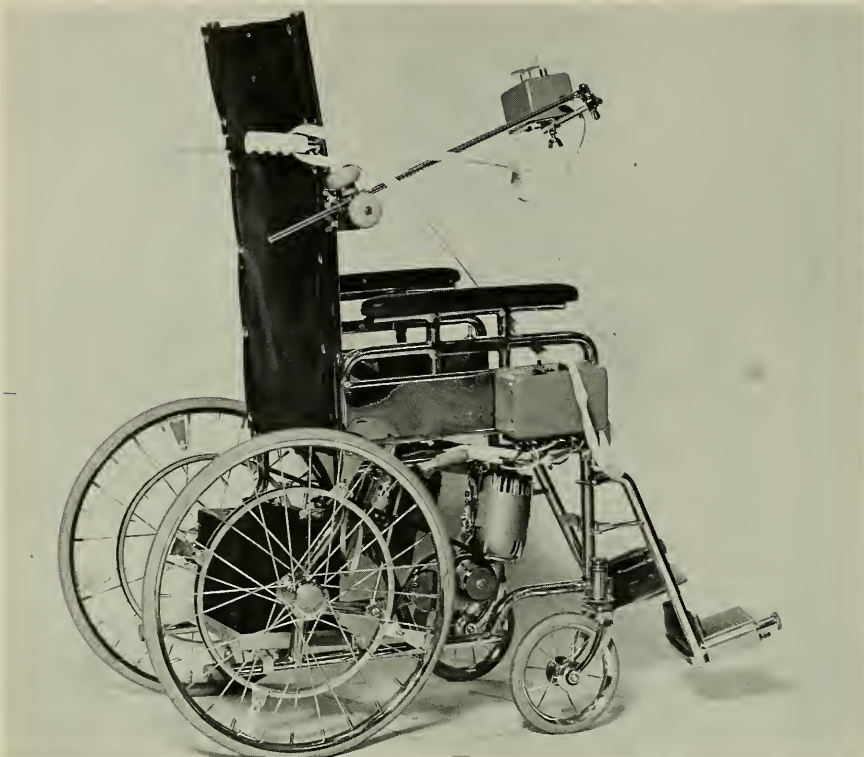
FIGURE 3.—Everest & Jennings Chin Control for electric wheelchairs.

FIGURE 4.—Sight Switch.
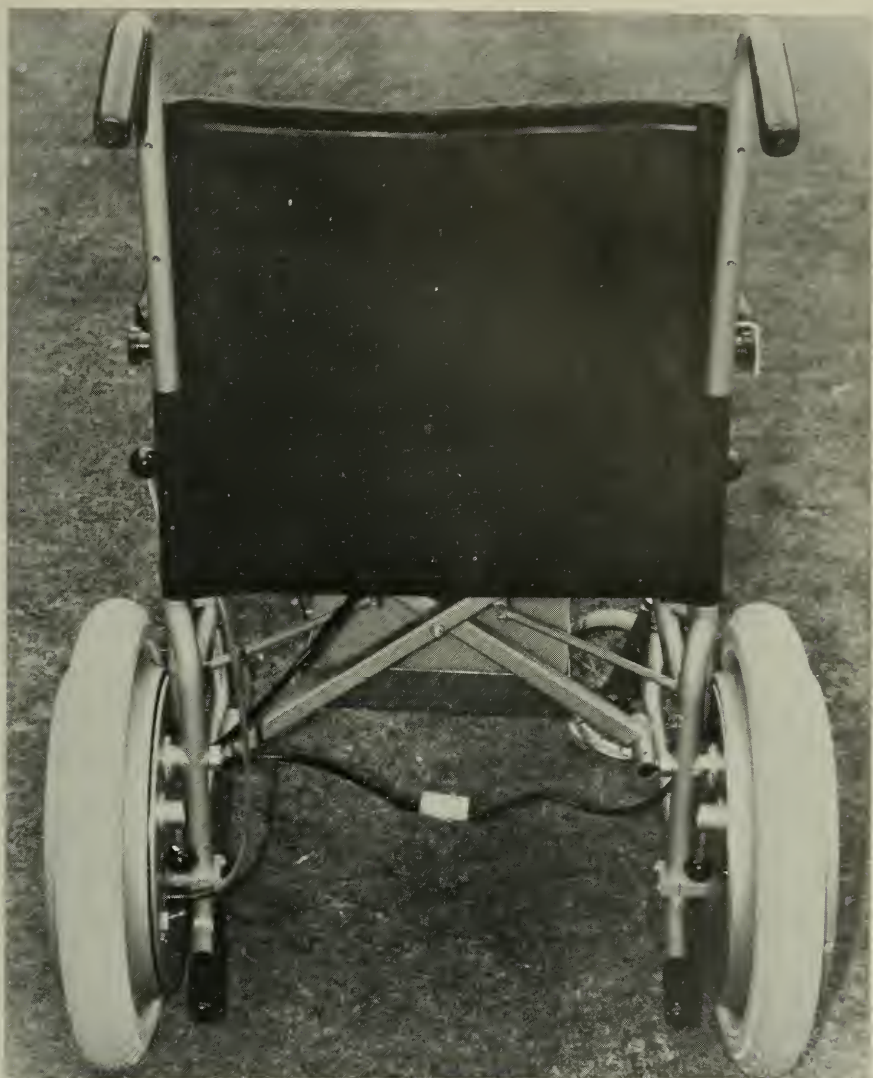
FIGURE 5.—Powered wheel.

must negotiate grassy and rough terrain as well as steep inclines. Even in urban areas, speed may be a critical factor, especially for those patients entering into traffic and crossing at busy intersections. It is not surprising, therefore, to see the emergence of more powerful electric wheelchairs such as Motorette's 24 volts power pack and Everest & Jennings experimental 24 volts system. Both powered chairs are able to attain speeds in excess of 5 m.p.h. Typical, conventional electric wheelchairs are generally able to attain speeds of up to 3 m.p.h. We, therefore, observe that the restraining environment of the hospital, institution, and

FIGURE 6.—A-BEC Powered Wheelchair.

home has partially retreated for many paralyzed veterans. The conventional electrically powered wheelchair is undergoing a metamorphosis into a higher performing nonlicensed vehicle, and a trend toward increasing performance is most apparent.

While the higher performing Everest & Jennings and Motorette 24 volts units superficially resemble their 12 volt counterparts, the Advanced Wheel Chair (Fig. 7) is substantially different in appearance although it provides many standard and desirable conventional wheelchair characteristics such as adjustable back, adjustable height armrests,

and adjustable foot rests. The Advanced Wheel Chair exhibits a superior structural distinction to accommodate the additional weight of motors, batteries, as well as significantly increased mobility stresses.

FIGURE 7.—Advanced Wheel Chair.

Recently, the golf-cart-type vehicle has emerged as the vehicle to provide increased performance. There is a potential problem that these mobility aids may require some sort of licensing by local traffic departments. Typical of the class of vehicles is the Everest & Jennings Mark 20 Power Cart (Fig. 8), Steven Motor Chair, and Zip Car, all especially suited for outdoor use. The interest for an ever higher performing

FIGURE 8.—Everest & Jennings Mark 20 Power Cart.

family of vehicles is being met by the application of gasoline-powered engines. This approach is illustrated by a powered front wheel such as that used in the Chair-E-Yacht (Fig. 9) and Para-Cycle (Fig. 10). The former vehicle consists of the powered front wheel followed by a platform and two rear supporting wheels. Upon the platform is positioned the wheelchair and its occupant. The driver may enter onto the platform by means of a small ramp which is readily raised by pushing a side lever. However, no tie-down system is available as yet and instability is an ever present danger. The latter mobility aid makes use of a powered wheel that attaches to both armrests of a conventional wheelchair. The powered wheel is then able to pull the wheelchair and its occupant at speeds in excess of 10 m.p.h. It is questionable whether or not the conventional wheelchair is able to sustain the severe stresses of highly increased mobility performance. It must be pointed out that these gasoline-powered vehicles are limited to outdoor use and may be subjected to state licensing regulations.

The Humanics Rehab-Chair (Fig. 11) is a powered vehicle that provides multifunction capability and permits its occupant to change his position and attitude. Multifunction, conventional, manually operated wheelchairs, such as the Overly-Bressler Stand-Up Wheelchair (Fig. 12), are appearing. While neither of these multifunction mobility aids is a final solution to the many needs of paralyzed wheelchair users, they are both illustrative of the variety of new types of nonlicensed mobility aids becoming available.

The trends in nonlicensed mobility aids are definitely dynamic in nature, and it is apparent that increased performance has become a recent but common need. The demand is obviously attempting to fill a void between the conventional electrically powered wheelchair and conventional licensed vehicles. However, to date, none of these systems has clearly filled this gap with respect to need, safety, practicality, and reliability. One may also question whether this desire to fill the void is worth the effort. Nevertheless, the trend, at this time, is clear.
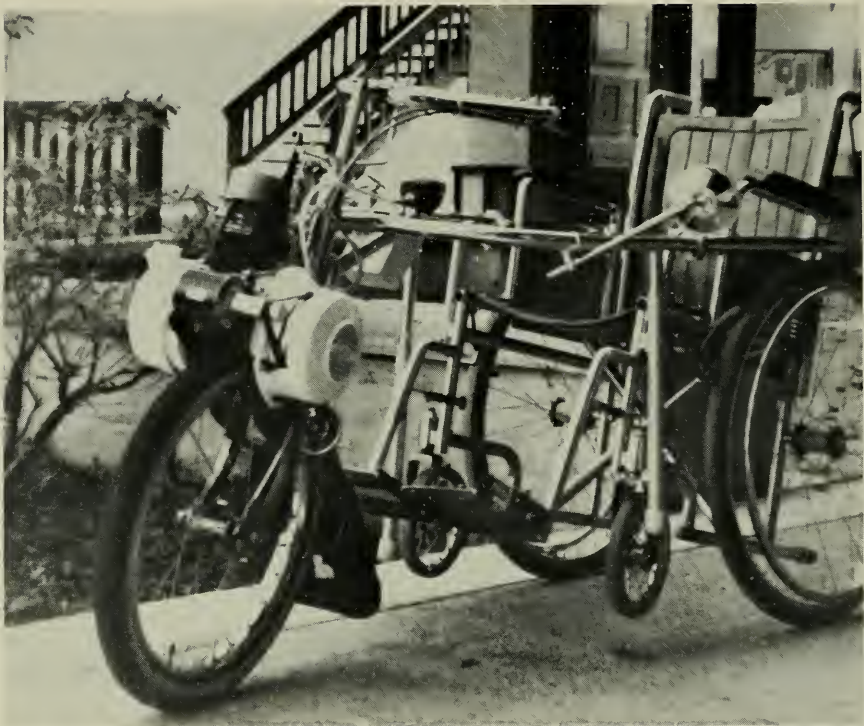
FIGURE 10.—Para-Cycle.
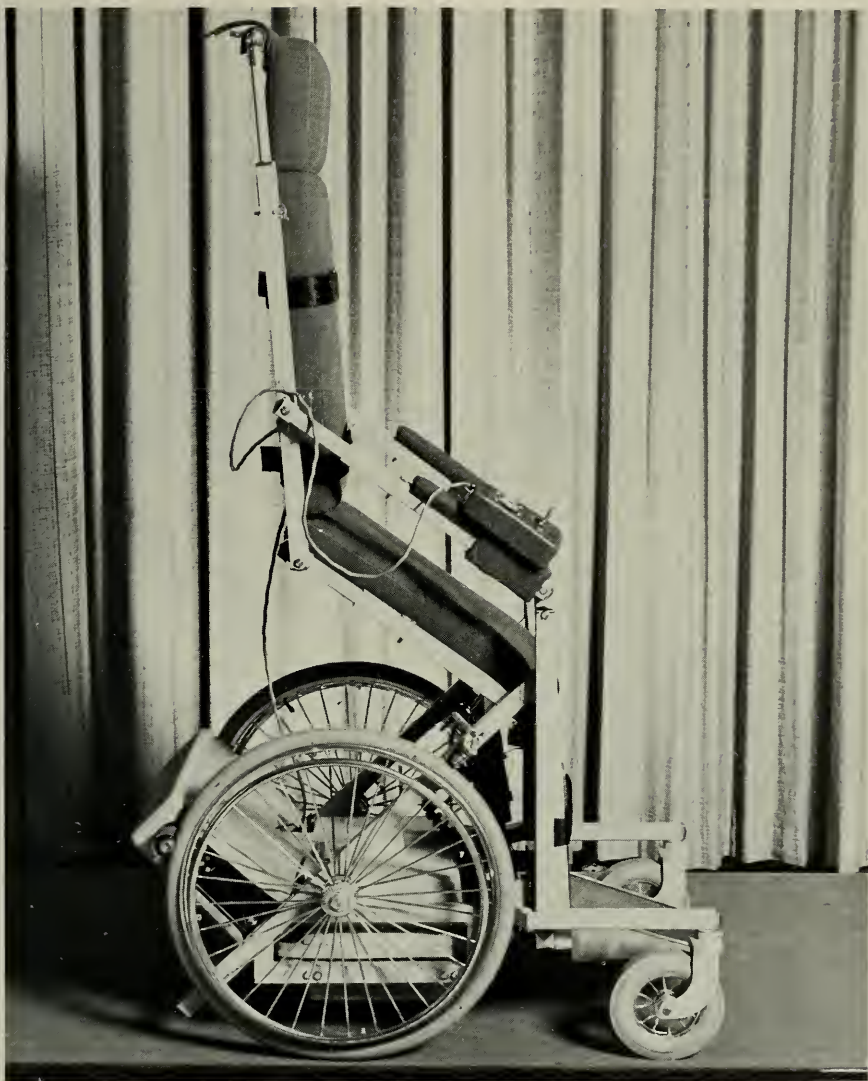
FIGURE 11.—Humanics Rehab-Chair.
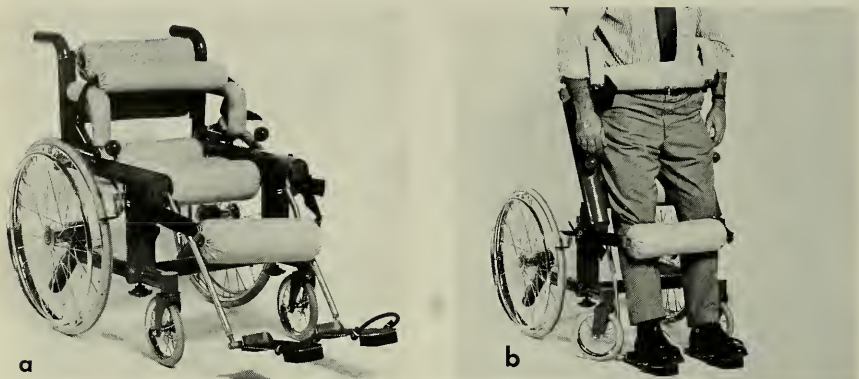
FIGURE 12.—Overly-Bressler Stand-Up Wheelchair.

AUTOMOTIVE AIDS FOR THE HANDICAPPED

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In attempting to define the "state of the art" of automotive aids for the handicapped, let us first consider the type of equipment available to consumers. Although a small amount of custom-designed automotive control systems serves some handicapped drivers, almost all drivers who do not have the use of their lower limbs depend on hand controlled brake-accelerator systems manufactured by approximately 18 companies in the United States. These add-on hand-control systems represent a wide variety of mechanical linkage mechanisms, conceptually dating back to after World War II when the availability of an automatic transmission eliminated the clutch pedal. Some manufacturers provide additional adaptive equipment—a variety of electrical or mechanical dimmer switches, parking brake extension, turn levers, shift levers, and an assortment of steering assists—to give the handicapped driver the particular assistance needed in operating the controls of an automobile.

Essentially the "state of the art" of adaptive automotive aids described so far has not changed very much over the last 25 years, whereas automobiles have changed a great deal to comply with stronger demands for safety. We note the now existing Federal regulations on the use of seat belts, the requirement of a collapsible steering column, etc., which have resulted in a general incompatibility between newer automotive designs and older add-on control systems for handicapped drivers. The installation of many commercially available hand-control systems to the variety of modern interiors of passenger automobiles has therefore become a very critical problem that, in the interest of public safety, must be fully realized and eliminated. At best, many of these old automotive hand-control systems are a conglomerate of bulky metal components, further cluttering the already tight space under and in front of the dash, and generally contributing only additional hazards in case of inertial changes of the vehicle.

We note with some feeling of encouragement that a glimmer of hope has appeared with the introduction of a specially designed servo-system for handicapped drivers. A production model of a vehicle featuring this servo-system, built by the VOLVO Co. of Sweden, has recently been

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introduced in the United States. In addition, several independent sources in the United States are currently working on advanced motor vehicle control systems for disabled drivers.

The "state of the art" of automotive aids for drivers who for one reason or another have chosen to operate van-type vehicles is very similar to the situation characteristic of commercially available add-on equipment. A variety of wheelchair access systems, wheelchair tie-down systems, and seating arrangements are advertised as specially equipped vans for the handicapped. Except for a few custom designs, these special vans are a more recently developed consumer item, and little is known as to the systems' reliability and performance. Considerable effort for further development of these vehicles is necessary, especially in areas of wheelchair transfer, tie-down systems, and seating arrangements for both handicapped drivers and passengers. The entire spectrum of automotive seating for the handicapped is a critical problem, requiring considerable work to provide adequate solutions. We strongly feel that current Federal Motor Vehicle Safety Standards should be implemented wherever possible to afford handicapped drivers and passengers at least the same protection given to the nonhandicapped motoring public.

We are confident that we are approaching an era where knowledge of the needs of the handicapped driver and passenger is no longer confined to a few groups, but that these needs are widely realized by many, including the automotive industry that must eventually play a major role in making available optional automotive systems for the disabled.

HEARING AIDS AND THE VETERANS ADMINISTRATION

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There are about 12 million people in this country who could benefit from the use of a hearing aid. At the present time about 3 million people wear hearing aids. Last year, hearing-aid manufacturers sold 600,000 hearing aids. These aids were sold by the manufacturers to their dealers for about $100 each. The dealers in turn sold them to the hearing-handicapped for about $350 each. The fact that components costing less than $30, when packaged, cost the hearing-impaired individual $350 is a cause of quite some concern at the moment. I suppose this concern has been just beneath the surface for some time, but at the moment, it is very much in the public view. In 1962, the Kefauver hearings on "The Prices of Hearing Aids" did not have the impact that the 1973 Church committee hearings on "Hearing Aids and the Older American" seems to be having. The big difference has been the consumer interest drive.

Concurrent with the Church hearings came the publication of the Nader Retired Professional Action Group Report called "Paying Through The Ear." This report attacked the dealers for the type of delivery system and prices of hearing aids, attacked FTC for not tightening trade practice rules for the industry, attacked the Food and Drug Administration for not developing standards for the industry, and attacked the American Speech and Hearing Association for not taking a stronger position in favor of better health care for the hearing-handicapped.

In order to put this discussion in proper perspective, let us review how the hearing-handicapped receive attention in this country. There are three major routes (Hearing Aid Journal, 1974) which the hearing-handicapped take to obtain help for their hearing problems (Fig. 1). About 75 percent of the individuals who come to dealers' offices come directly, without referral from either an audiologist or a physician. About 10 percent come from referral by a physician, and 15 percent come from referral by an audiologist or hearing and speech center. The audiologist requires that a hard-of-hearing patient have an otological examination or an examination by his family physician before the audiologist will measure hearing or conduct a hearing-aid evaluation.

Since many hearing problems may be a manifestation of pathology that is potentially a threat to the patient, the audiologist has long insisted on proper medical clearance of the patients he sees. Yet, according to a survey of hearing-aid dealers, 82 percent of the dealers who responded indicated that a medical examination was not necessary for all persons who wished to purchase a hearing aid. The ethical standards of the American Medical Association and the American Speech and Hearing Association have prevented either the ear specialist or the audiologist from engaging in the sale of hearing aids directly or indirectly. They are allowed to make referrals to dealers from whom the hearing aids may be purchased. This kind of delivery system for a sensory aid has the effect of keeping prices high, interrupts the normal flow of patients to physicians, and deemphasizes the need for counseling and training in the use of the hearing aid required to insure that the individual will make maximum use of it.

Present Routes to Hearing Aid
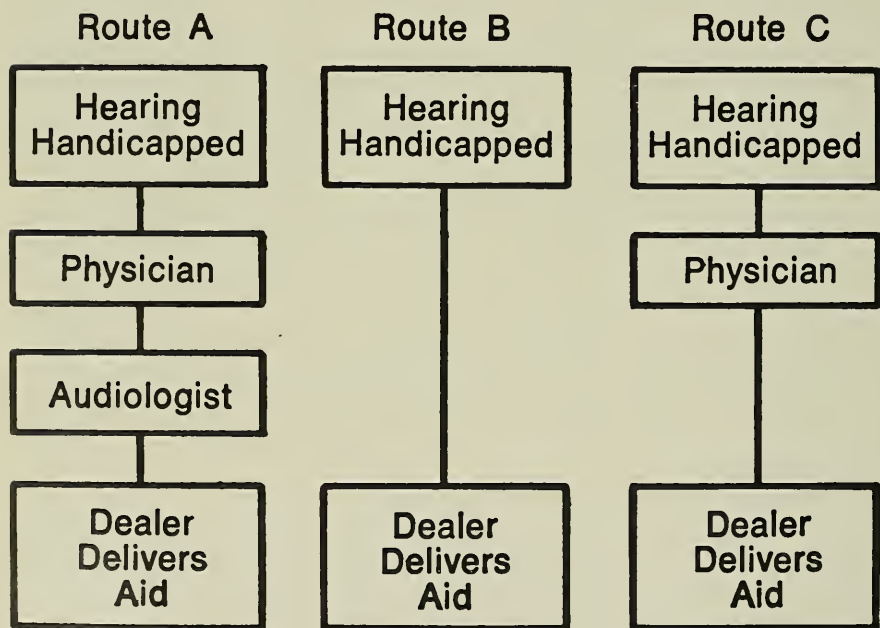
FIGURE 1

In 1967, a panel established to discuss professional qualifications and standards at a Conference on Hearing Aid Evaluation Procedures considered the question of the present system for hearing-aid evaluations and how it could best be improved (Castle, ASHA Reports, No. 2, 1967).

They recommended that audiologists become directly involved in the dispensing of hearing aids. All too often the audiologist recommends a hearing aid and then never sees the patient again, even though a followup visit has been scheduled. The typical dissatisfied hearing-aid user does not return to the audiologist or physician who recommended the instrument, but rather to the hearing-aid dealer from whom it was purchased. The ability of the audiologist to improve the accuracy of his recommendation can best result from the knowledge he has gained from proper followup of his past recommendations. The audiologist has been placed in an unusual position in this regard. This is somewhat like a physician who is allowed to make the decision that surgery is to be done, but who is only sometimes informed of the results of the surgery or the adequacy with which someone else carried out his decision. Such a situation is obviously intolerable if improvements in service both before and after the selection of a hearing aid are to be made by the audiologist. Increased involvement by audiologists will lead to increased amounts of research data considering the physical characteristics of hearing aids, the criteria by which a given ear is matched to a given instrument, and new ways of using hearing aids.

Since that recommendation was made in 1967, the profession of audiology slowly but surely has worked around to a position whereby the dispensing of hearing aids may be done if the audiologist does not profit from such action. In other words he may charge a fee for service, but may not add to the invoice price of the hearing aid he obtains from the manufacturer. This approach is diagramed in Figure 2 (Hearing Aid Journal, 1974). As you may suspect, there is widespread consternation among hearing-aid dealers because of this approach. On the other hand, some dealers, recognizing a revolution approaching in the way in which hearing aids are delivered to people, have changed from a system of salesmen operating in the field, and especially in the homes of the hearing-impaired, to a referral system from physicians and audiologists. These dealers now sell hearing aids only upon referral from these specialists, usually at a much reduced price.

I have discussed the American Speech and Hearing Association, the Nader report called "Paying Through The Ear," the Kefauver and Church hearings. What is FTC doing at this time? They are suing some of the major hearing-aid companies for anti-competitive practices and illegal advertising. But more importantly, they are writing a consumer advisory entitled "What You Should Know Before You See A Hearing Aid Salesman." In addition, they are about to hold a hearing on a completely new set of trade practice rules for the hearing-aid industry. The thrust of the new rules is to provide a guarantee of money back to the purchaser of a hearing aid who is dissatisfied. What is the Food and Drug Administration doing at the moment? They have asserted that a

hearing aid is a medical device, and therefore it is that agency's responsibility to develop standards for it. Accordingly, the FDA 2 months ago announced to the hearing-aid industry and the American National Standards Institute that they must develop a performance standard for hearing aids within 12 months or the agency would develop its own performance standard for hearing aids. The American National Standards Institute Committee on Hearing Aids is made up of engineers from the hearing-aid industry, audiologists, and physicists. There presently exists a standard for the measurement of hearing-aid performance and a standard for expressing that performance. However, no standard has ever been attempted which would provide acceptable limits of performance such as FDA has in mind. You cannot imagine the surprise within the group when the intention of the FDA was announced.

Proposed New System

HEARING
IMPAIRED
INDIVIDUAL

PHYSICIAN

AUDIOLOGIST
(evaluates
and
recommends)

AUDIOLOGIST
(dispenses
aid as
part of
Comprehensive
Rehabilitation
Program)
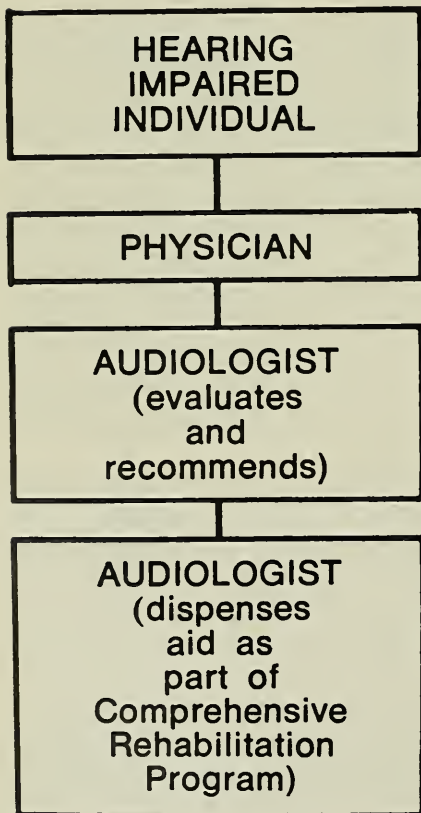
Figure 2

For the last 6 years the standards committee had been working slowly to adopt a change in the measurement standard which would substitute for the present coupler used for measuring hearing aids—a new coupler which better resembles the performance of the human ear. The discussions of the committee have dragged on for over 5 years, and it looked as though it might be another 5 years before accord could be reached regarding substitution of the new coupler. Incidentally, the present coupler was developed over 20 years ago, just as an interim measure anyway. The effect of the FDA announcement was to unite everyone behind the new coupler and try to dispose of the revision of the measurement standard as soon as possible in order to develop the performance standard within the deadline.

What is the situation with regard to hearing aids within the Veterans Administration? In the 1962 Kefauver hearings, the Veterans Administration received glowing praise (Subcommittee on Antitrust and Monopoly, Prices of Hearing Aids, 1962). In the 1973 Church Committee Hearings, the Veterans Administration was discussed as a model for future government involvement with hearing aids (Subcommittee on Consumer Interest of the Elderly, Hearing Aids and the Older American, 1974). To quote the Nader report, "The Federal government is doing virtually nothing on the subject of hearing aids, with the exception of the Veterans Administration." One complete chapter of the Nader report was devoted to the Veterans Administration program. What is the Veterans Administration program? The Veterans Administration has been dispensing hearing aids on a large scale through their Audiology Clinics since 1956. At the present time there are 46 centers engaged in this activity. Twenty percent of their workload is devoted to hearing-aid evaluations. As shown in Figure 3, 11,099 hearing aids were issued by VA clinics last fiscal year, 2,724 aids were issued by the military, 578 aids by other government agencies. The average cost of those 14,401 hearing aids was $86.78. It costs the Veterans Administration $84,000 to have hearing aids measured at the National Bureau of Standards, and it costs about $80,000 to maintain the individuals working at the Hines Supply Depot involved with hearing aids. The Supply Service has to recover this money, and it does so by marking up the price of hearing aids about 14 percent so that the average cost of an aid with the markup is $100.91. The depot buys the hearing aid at an average cost of $86.78 and sells it in turn to the various hospitals in this system or to the military for $100.91. The lowest costing aid is the Zenith Award which costs, with the markup, $41.54, and the highest priced aid is the Sonotone 35 AX BICROS at $157.06.

The selection of aids for contract is accomplished by following a program designed to take advantage of all known psychophysical data related to hearing rehabilitation. When this program was initiated, a

Aids Issued For Fiscal Year 1974

VA Clinics	11,099
Military	2,724
Other Gov't Agencies	578
Total For The Above	14,401

Average Acquisition Cost (without the markup)	$ 86.78
Average Cost Per Aid (with the markup)	$ 100.91
Cost of all Hearing Aids Purchased in 1974	$ 1,453,219.54
Lowest costing aid is Zenith Award (with markup)	$ 41.54
Highest priced aid is Sonotone 35 AX (with markup)	$ 157.06

FIGURE 3

group of consultants appointed by the VA developed a series of procedures for determining the electroacoustic performance and characteristics of hearing aids. These procedures are reviewed and reevaluated each year on the basis of new research and clinical findings. Each instrument is tested at the National Bureau of Standards and/or at the Biocommunications Laboratory, University of Maryland, under exacting conditions. The analysis of these data is performed by the Auditory Research Laboratory, Veterans Administration Hospital in Washington, D.C. The electroacoustic attributes of the hearing aids are assigned specific weightings based upon their importance as determined currently by the hearing-aid consultant group. The weighted scores for the several characteristics are then summed to obtain an Index of Characteristics score that represents the performance of each hearing-aid model. This system provides the Veterans Administration with quantitative information on which to base hearing-aid purchases for its beneficiaries. Gain, saturation SPL, frequency response, nonlinear distortion at two input levels, signal-to-noise ratio, signal-to-hum ratio, and measures of uniformity of slope, product uniformity, and other data are obtained.

To provide sufficient data on which to judge the performance characteristics of the specific model being evaluated, three sample hearing aids of each model are required for these measurements. Manufacturers are limited to the submission of seven different models, a total of 21 instruments selected from his line of head-worn and on- the-body-type hearing aids.

The results of this annual measurement are published both by the Veterans Administration and the Government Printing Office and are available to the general public.

For Fiscal Year 1975 there are 33 hearing aids on contract. These are broken down into power categories and into categories of hearing aids with special characteristics. In the strong power category there are four on-the-body aids on contract; in the moderate power category there are five hearing aids of over-the-ear type, and two eyeglass aids. In the mild power category, there are three over-the-ear aids, one eyeglass aid, and one all-in-the-ear aid. In the special category, there are four CROS hearing aids. A CROS hearing aid has a receiver on one side and microphone on the opposite side; these are in eyeglasses. There are three BICROS hearing aids, also in eyeglasses. For the BICROS aid there is a receiver going to one ear, but a microphone in both temples. There are two body aids especially designed for the elderly. They are rather lightweight and have large controls with quite visible markings. There are two hearing aids with directional properties. In other words, they amplify sounds occurring from in front of the individual, but amplify to a lesser degree sound occurring behind him. There are three hi-pass hearing aids which amplify the high frequencies only. Finally, there is one eyeglass bone conduction hearing aid and two hearing aids with compression characteristics. These latter hearing aids tend to maintain a constant output regardless of the level of the input signal.

The veteran who is eligible for treatment of a hearing disability may apply for a hearing aid to the nearest VA center. He is given an appointment for an otological examination followed by an audiological examination. Upon determination of need for a hearing aid, a hearing-aid evaluation is conducted. When the veteran is issued a particular hearing aid, he also receives a 2-week supply of batteries. The Prosthetic Distribution Center in Denver is notified by card that the veteran has been issued a hearing aid. The veteran immediately is sent a 90-day supply of batteries for that instrument. On the average, a 90-day supply of batteries costs $2.94. Parenthetically, let me add that last year the Veterans Administration issued 1,672,287 batteries at a cost of $235,610. That is an average cost of 14 cents apiece. The veteran also receives from the Prosthetic Distribution Center a preaddressed mailing carton with instructions relating to packaging the hearing aid and to sending it to the Center anytime it requires repair services. Minor repairs and maintenance services are completed at the Center. The instrument needing factory repairs is sent to the manufacturer or other commercial repair facility. The repaired hearing aid is tested at the Center to determine if it is satisfactory before being returned to the veteran. Last year, 16,587 repairs were made by commercial resources at an average cost of $14.77 apiece. The Prosthetic Distribution Center

made 11,000 small repairs or provided tubing, cords, or receivers, at an average cost of $1.83 apiece. For the hearing aids currently issued there is a 2-year warranty period. Eligible veterans are provided spare hearing aids to utilize when their regular hearing aid is sent in for repairs so that they will not be deprived of aided hearing. Ordinarily, the veteran who receives an initial hearing aid may return after 6 months for a second instrument. The first one issued then becomes his spare aid. Studies have shown that the majority of veterans retain their hearing aids longer than the average citizen. You may note in Figure 4 that 50 percent kept their regular hearing aid for 8 years or longer before applying for replacement instruments, and 29.3 percent kept them 12 years or longer.

In a sample of 700 veterans, the following distribution indicates the length of time veterans wear their aids before obtaining a replacement. Mean = 8 years.

TIME	N	%
1 year	27	4.1
2 years	32	4.6
3 years	45	6.4
4 years	51	7.3
5 years	53	7.6
6 years	45	6.4
7 years	43	6.1
8 years	64	9.1
9 years	46	6.6
10 years	49	7.0
11 years	45	6.4
12 years	38	5.4
over 12 years	160	22.9
	700	99.9

FIGURE 4

A preliminary study has shown that it costs the VA $219 to issue a hearing aid. This includes the cost of the aid, professional and secretarial services, the earmold, and overhead at the rate of 38 percent. This figure includes 6 hours of an audiologist's time spent in counseling, auditory training, and orientation on a group basis.

Where does VA stand as far as its needs are concerned and the current state of the art? There is a need for hearing aids of better quality and of more uniform quality, and it can achieve this only by improving its own measurement program and measuring the performance of every aid it buys from the manufacturers throughout the year. Because VA can make decisions quickly without polling the industry or getting unaimous verdicts, it can forge ahead with new developments and new techniques. This is certainly indicated by the discussions generated in the meetings of the American National Standards Institute. For example, the Committee on Hearing Aids is considering using the VA procedure for determining volume control setting for the measurement of gain, to-

gether with the utilization of shaped noise as an input signal for measurement of saturation sound pressure level. These two items were innovations introduced to the field by VA some years ago. Other innovations have been techniques for measurement of directional hearing aids and techniques for measurement of compression hearing aids.

Insofar as the current state of the art is concerned, VA is well ahead of others. However, because VA is constantly in the spotlight and VA's motto is "Health care second to none," it must be our function to remain well ahead.

READING AIDS FOR THE BLIND

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SCOPE OF THE ARTICLE

This article concerns inkprint reading aids for people who cannot use optical aids or closed-circuit TV systems. Available reading devices and some current research are described and discussed. The paper concerns work with adults, though there are many implications for children.

HISTORY

Before escorting you into the microcosmic world of reading aids, let me supply some background. In 1913, a British physicist, Dr. E.E. Fournier d'Albe described a reading aid for blind people and later built a crude model. A young woman, Mary Jameson, demonstrated it. Then a British engineering firm, Barr and Stroud, redesigned it and built six copies. Several blind persons have used them down to the present. Miss Jameson, the first user and teacher of the skill, is today active in the field.

The British device is the first member of the optophone family. *Optophone* is the name for a class of machines which converts letter shapes into tone patterns. As the probe or camera is moved horizontally, each tone responds to an assigned portion of the letter along its vertical axis. For example, a letter V is heard as a descending scale of sound followed by an ascending scale. The letter I is heard largely as a chord because several of the photocells "see" the print simultaneously.

Through the years, several designs of optophones have been built. The British machines first had five channels or tones; then they were given a sixth. Twenty years ago, I read that Mary Jameson was reading her mail and checking her typing, and I decided to seek an opportunity to use a reading aid. So 10 years ago, I learned to read with a device the size of a train case which had nine tones. It was called the VA-Battelle optophone. For many years after World War II, the VA was responsible for most reading-aids research done in this country, and this machine designed at Battelle Memorial Institute, Columbus, Ohio, was a VA project. In 1966, I taught Margaret Butow to read with it. She is now teaching the use of the Stereotoner at The Hadley School for the Blind, Winnetka, Illinois.

In 1967 the Visotoner came onto the scene. The Visotoner is an optophone made by Mauch Laboratories of Dayton, Ohio, under VA sponsorship. In that year, I began working full time as a reading-aids specialist in the VA. In 1973 Mauch Laboratories began manufacturing the Stereotoner. It is the latest form of optophone, and I shall describe it later.

OTHER AUDIBLE DEVICES

Over the years, a number of designs have been proposed. The RCA A2 reading machine was a project of the 1940's. It used a raster which scanned vertically. The Canadian lexiphone and the Russian optophone are among research efforts of the 1960's. There are also basement laboratory designers who propose reading aids consisting of single-channel optical probes. These make good light detectors but have severe limitations as reading aids.

TACTILE OUTPUTS

One of the first reading aids to have a tactile output was the Visotactor. It was built by Mauch Laboratories in the early 1960's. Its eight vibrating pins are felt by four fingers of the right hand. Several people learned to use it, but it is now considered obsolete and is not presently used. Extensive research is going on at Smith-Kettlewell Institute, San Francisco, California, on tactile outputs for sensory aids. Other efforts throughout the world range from the modest to the ambitious. Parts of the body including the back, the stomach, and the forehead are under consideration. Most recently, electrical stimulation of the brain is being studied.

THE OPTACON

The Optacon is the result of extensive research begun in the early 1960's at Stanford Research Institute and Stanford University. It has been on the market for 3 years and is manufactured by Telesensory Systems, Inc., Palo Alto, California. The firm's president, Dr. James C. Bliss, had a large part in the Optacon's development.

The word Optacon derives from *op*tical to *ta*ctile *con*verter. It measures $2 \times 7 \times 9$ in.; the instrument has a probe or camera, electronic circuits, and a matrix of vibrators. The matrix or array of vibrators consists of six columns and 24 rows and is felt by one finger. The array vibrates in the shapes of the print symbols as the user tracks the print with the camera held in his other hand.

Eight hundred Optacons have been sold throughout the world. The price is $3,450, and a service contract is available costing $200 per year after the first year. A number of data processors are among its most enthusiastic users.

A newly-designed tracking aid is available. Another accessory is a visual display monitor by which a sighted teacher can monitor the student's reading. A blind teacher can do this by connecting another Optacon to the student's machine. Usually the teacher's own machine is used for monitoring.

THE STEREOTONER

Designed under contract with the VA Research Center for Prosthetics, the Stereotoner is manufactured by Mauch Laboratories, Inc., Dayton, Ohio. It measures $4 \times 5 \times 1\frac{1}{2}$ in. and is usually worn on the chest while reading. As its probe is moved along a line of print, a 10-tone (10-channel) code is heard stereophonically in earphones. Each tone is heard at a different volume in each ear. High tones are heard louder in the right ear and softer in the left. With low tones, the situation is reversed. The letter V which was described earlier also sounds as if it moves from side to side. The price of the Stereotoner is $1,120. About 75 machines have been sold.

A ruler-shaped tracking aid is provided. This facilitates tracking for users, but beginners need a more elaborate version. Monitoring is done by connecting a second set of earphones. An accessory which permits visual monitoring is also available. About 25 people are using Stereotoners, most of them having been trained within the past year, so data on long term usefulness are not yet available. Several typists are among the enthusiastic users of the Stereotoner.

DEMONSTRATIONS

After years of lecturing and demonstrating, I have concluded that the biggest mistake an interested person can make is to form a firm opinion either for or against a given reading aid after a lecture and brief demonstration. Few people are equipped to judge their ability or lack of ability to learn to use rapidly presented tonal or vibratory patterns. Even fewer people understand the several tasks involved in using an aid — the interaction between man and machine.

Typically, the demonstrator slowly presents to the observer some simple letter shapes. This is done to show the principles of operation and the intelligibility of the signals. The experience leads some to conclude that the skill is easily mastered while others are frightened by its apparent difficulty.

The observer's reaction seems to depend as much on his self-image and his perception of reality as he does on his abilities and the quality of the demonstration. On some occasions, however, a skilled user demonstrates by reading normally while the observer listens to the sounds of the Stereotoner or feels the output of an Optacon. The observer then

reacts in whatever ways he customarily reacts to the performance of a well-trained athlete, magician, or psychic. Such diverse reactions also occur as people watch braille being read for their first time.

Demonstrations are suitable for the casually interested. For the deeply interested, we should provide demonstration, experience, tests, and counsel.

TRAINING

Learning to use a reading aid is much like learning a second language. Self-training is not recommended. From 2 to 4 weeks of fairly intensive training is given, which should be followed by several months to a year of regular practice. Ideally, before a wise decision is made, several hours of experience and tests with each machine are needed.

UTILITY

Reading aids are used chiefly for tasks requiring small but important amounts of reading. These include checking one's typing (often while still in the typewriter) and reading correspondence, bills, memos, definitions, recipes, currency, etc. Reading handwriting is seldom attempted and rarely done. Few people read books and newspapers because braille, recordings, and radio are much faster. Speech compressors should soon cost under $200. They will make reading by listening even more efficient. Some business machines can be equipped with braille or audible outputs which do not require use of a reading aid. These alternatives should be studied and reported to consumers.

On the other hand, many developments in technology and standardization favor the use of reading aids. For example, a typewriter equipped with an erase feature used by a blind typist equipped with a reading aid add up to an efficient and rewarding combination.

Reading aids provide for improvements in the lifestyles of certain people. It takes many people a year or so to reorient their habits and skills before they know exactly how the aid will fit into their lives. The decision whether to acquire an aid and be trained is made more difficult by the changing environment of modern life, the newness of the aids, lack of good studies of their utility, and the glamorization of sensory aids for the blind.

STUDIES OF UTILITY AND READING RATES

At present, reading rates and the usefulness of reading aids are difficult to assess accurately. Most testing has been done while students are in intensive training where rates and utility are naturally low. After training, data are usually obtained through questionnaires and telephone interviews. Generally, such data are unreliable because users'

estimates of their reading rates are often inaccurate, and their estimates of how efficiently they use their aids are very subjective. What is additionally needed is an independent study of people who have used reading aids for at least 1 year, and those who have discontinued their use. A test battery should be given to determine reading rates and skills at whichever tasks are appropriate to individual users. Anything short of such a study runs the risk of being a disservice to consumers and organizations who invest time, money, and effort. When the successful users are identified, we can give informed counsel to candidates.

In the absence of suitable followup data, there is little to be said about reading rates. Attainable rates vary widely. A minority of users read around 10 words per minute. Speeds in excess of 60 words per minute are fairly rare. A low-speed user with lots of time to spend may be happier than a high-speed user who is in a hurry. It will be possible to predict more accurately the attainable reading rates of candidates when further research results are available. We look forward to the research findings of two projects conducted by the American Institutes for Research, Palo Alto, Calif. These are the Optacon Project sponsored by the U.S. Office of Education and the Stereotoner Project sponsored by the VA.

COMPARABILITY

To make a facetious beginning, both Optacon and Stereotoner can "see" the print. There are differences in the range of sizes and colors which each machine will accommodate. There would be little value in listing these specifications without adding pages of information about the world of print.

Reading by means of the sense of hearing requires less hardware, so the Stereotoner has less circuitry and fewer moving parts. This gives it advantages in size, cost, and maintenance. One hand is also free for handling materials or tracking. These advantages, however, only help those people who can learn well its 10-channel audible code.

Since the Optacon has 24 rows of vibrators, it delivers more information or detail about letter features than does the Stereotoner. This additional information, however, is useful only to those who can perceive this detail with a finger.

A choice machine should be based on testing and trials. Experience has sadly shown that it is a mistake to base one's decision on such things as proficiency with braille, musical background, or attitudes about the signals.

Each of my students is given tests and experience with both machines. Of my last eight students, four were taught the Optacon and four the Stereotoner. This means only that I did the best I could with the available materials. It does not mean that 50 percent of the people need each

machine. That percentage will best be found after more research findings are available.

BLIND TEACHERS

I teach the use of both machines. I have been trained with both, and I can read with both, but I personally use the Stereotoner. This is because the tonal code was first available to me and because I have higher potential for it. It is very advisable for a blind teacher to use one machine proficiently. The second machine should be learned to the point where the teacher can completely monitor his student's reading.

HUMAN FACTORS IN LEARNING THE SKILL

Learning to use a reading aid is like learning a new language. Patterns must be apprehended subconsciously as letters and words. For example, the Stereotoner code is in my subconscious. To install the Optacon code in my subconscious would require much motivation and practice.

There develops a complex, "intimate" man-machine relationship. The degree of involvement or "love affair" one has with a reading aid is greater than the investment needed in becoming a skilled typist but less than the investment needed in becoming an accomplished musician. Occasionally, we encounter the exceptional person who learns the skill quite easily. Such people have either exceptional ability or exceptional motivation.

The following is an example of one among several interesting hypotheses. This man-machine relationship seems to favor the type of person whom the psychologist Dr. Stanley Martindale calls *verbal* over the *anomic* person. He says the *verbal* person (30 percent of the population) is one who relates best "self to object," and the *anomic* person (70 percent) relates best "self to person."

One caution we give to potential students is to keep an open mind about their abilities and lack of abilities. We also recommend that newly blind people first avail themselves of other needed rehabilitative services before they consider a reading aid. Those who have remaining vision should also first try low-vision lenses and closed-circuit TV systems. Generally, students who are learning to use a reading aid find the training to be challenging and rewarding.

MY SUGGESTIONS

Based on my experience, I also submit the following suggestions: 1. Students should be encouraged to learn the skill only when long term loan or purchase is highly probable. 2. Agencies which lend reading aids should do thorough followup to see that the aids are in use and not in closets. 3. There should be a rental option for those who buy aids. This

need not apply to agencies for the blind. Agencies can transfer the aids to other users if necessary.

TRACKING AIDS

I must discuss tracking aids or my colleagues will count me remiss. Some users and most beginners do not have the coordination needed to track print well by hand. Tracking aids have often been inadequate because of initial over-optimism as to the difficulty of the task and because designers who work hard to miniaturize both hardware and costs are reluctant to admit that their "brain children" need mechanical help. Suitable tracking aids for current reading devices became available some time after production models first appeared. Teachers who do not have experience with a good tracking aid do not know what they and their students are missing.

Beginners may also be helped by motor-driven pacing aids. The modern versions are expensive and complex, but the British had a simply operated one for their first Optophones. Good instructional manuals have been slow in coming, but the new ones are greatly improved thanks to the American Institutes for Research and the equipment developers.

POPULATION AND FUTURE NEEDS

Let us turn now to demographics. The American Foundation for the Blind, in its telephone survey of Optacon users published in *The New Outlook for the Blind*, February 1974, says: "AFB estimates that perhaps 10,000 people in the United States and Canada . . . might be potential users of the Optacon." Further study may show this estimate to be a little high. I would say that several thousand people in the U.S. can use one reading aid or the other.

Now let us look at the picture for veterans. John Malamazian, Chief, Blind Rehabilitation at Hines Hospital, gives the following figures which he and others in the VA have compiled. Eighteen thousand legally blinded veterans have been identified. There may be 2 or 3 thousand more who have not yet been identified. About 4,000 are totally blind. Most are World War II veterans. Many of them lost their sight after leaving the military service. There are less than 1,000 totally blind people, mainly men, who are below age 55. I estimate that about 150 veterans will be interested in reading aids and will be eligible for them.

Let us turn to the world picture. According to the British Royal National Institute for the Blind which has facilities in all parts of the world, there are 15 million blind people in the world. Because of high incidence of blindness among young people in less developed countries, 5 million of this total are of working age. Though the literacy rate in

much of the world is low, a world market would certainly make production of reading aids more efficient.

SOME PROSPECTS FOR THE FUTURE

So far, we have discussed what are called "direct-translation" reading aids. Current machines, the Optacon and Stereotoner, do not (intentionally) process data. Instead, they provide the user with signals depicting the shapes of symbols "seen" by their electro-optical systems. Suppose now that we add to such a direct-translation reading aid logic circuitry so that it will give us the identities of letters. We would then have an Optical Character Reader, commonly dubbed an OCR. Industry has OCR machines feeding alpha-numeric data to its computers. They are accurate, and they feed data faster than we humans could handle it. However, they are bulky, enormously expensive, and too limited in the number of type styles they will accommodate to cope with the world of print faced by the office worker and homemaker.

Among several projects to build a personal OCR for blind people are those of MIT, Israel, Canada, and the VA. The VA project conducted at Mauch Laboratories will be described here.

Mauch Laboratories calls their design the Cognodictor. It incorporates a reading aid like the Optacon or Stereotoner with which the user must track the print, adjust for print size, and read whichever symbols the machine's logic circuitry is not programed to identify. These include numerals, punctuation, unusual print styles, and "damaged" print. However, when so-called "good" print is encountered, the machine "talks" to him in letter sounds or spelled speech. In short, the user must learn to use a direct-translation machine with which he would read such things as bank statements. However, when the body of a magazine article is to be read, the minicomputer will function permitting reading rates of 100 plus words per minute. The cost will be several thousand dollars.

The concept of the Cognodictor was partially but successfully tested with past designs. In 1971, several blind people, myself included, used a model of the Cognodictor with spelled-speech output. In my opinion, at the present rate of development, there will be a new prototype in 2 years and a production model in 4 years. Some of my colleagues feel that less time will be required.

Let us now look beyond the personal reading aid. A library book could be transcribed into recorded form by a computer. This job may take a team of computers. The spoken-English output of such a system is being researched in a VA project at Haskins Laboratories, New Haven, Connecticut. This output would also be useful in a time-shared arrangement with a large computer. Under such an arrangement, the user would telephone the computer for service. He might then have to track the print with his small machine with which he could also read indepen-

dently. The computer would then read "over his shoulder," so to speak, and speak to him over the phone in his native tongue. MIT and Stanford Research Institute have also done work in this area. Presumably, if and when computer terminals become common in our homes, then computers may also help us read. Our glimpse into the future has shown that future developments, rather than making present skills obsolete, could make those skills more valuable.

CONCLUSION

The Optacon is being well received by many. Its manufacturer has a training facility as do a number of agencies. The Stereotoner is being introduced into several training facilities including The Hadley School for the Blind. Hadley also has a pretraining tape-recorded course which will be revised for the Stereotoner. This recorded course will introduce the skill and prepare people for training at Hadley or elsewhere. As we learn about the Stereotoner's applications and the kinds of people who can use it, it should take its place among rehabilitation tools.

I do not state the case for reading aids as strongly as those who say that they open up a new world for blind people. I do state the case as follows: The reading aids offer certain people a bit of synthetic eyesight.

MOBILITY AIDS FOR THE BLIND

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Most independent mobility of people who have no useful travel vision, especially when in unfamiliar territory, is achieved through use of some mobility aid. Mobility and mobility aids are rather inextricably tied together, so I shall recount some needs of the VA in mobility rather than only in the more limited field, mobility aids.

NEEDS OF THE VETERANS ADMINISTRATION

I hesitate to tell you, with appropriate adjustments for mobility, that we need improvements that could be classed as "Motherhood Apple-Pie" items, yet not to mention them could suggest they are being overlooked. With the aid of several colleagues in the sensory-aids field I have compiled the following list of needs of the VA in mobility for the blind:

1. Next to restoring vision, or a modicum of vision, an ideal mobility device is desired. It should be able to give the user data on his location, orientation, routes, compass courses, obstacles, etc.
2. Increase the awareness among consumers and professionals alike of the availability of new devices such as the Laser Typhlocane, Binaural Sensory Aid, and Lindsay Russell Pathsounder.
3. Improve public information and public relations activities regarding VA's blind rehabilitation programs.
4. Develop selection and prescription criteria to aid in reaching the best solution to the mobility problems of each blinded person.
5. Obtain a better understanding of the influences of other disabilities a blind person may have on the mobility means of choice, and the performance to be expected. It has been estimated that only 10 percent of blinded veterans are free of some other significant disability.
6. Increase the number of blinded veterans who receive orientation and mobility (O&M) training at a VA blind rehabilitation center (BRC) or equivalent activity.

7. Build up the cadre of instructors capable of training blind people to use the new mobility aids.

8. Provide followup contacts and counseling and offer periodic refresher training in mobility as blinded veterans go through life.

9. Provide improvements in reliability, ruggedness, and performance capabilities of devices.

10. Improve collapsible canes— more durable, longer lasting.

11. Provide a special evaluation and training model of the Laser Typhlocane with complete flexibility as to which channel(s) and display(s) are on or off.

12. Improve telemetry equipment for mobility devices, with capability of monitoring from more remote locations than at present. Provide transducers and telemetry system for recording human stress levels as subject performs a mobility task.

13. Do more work on image intensifier devices for use in mobility of the "night blind," with price reductions in these devices.

14. Reduce costs in device acquisition, client training, followup, and maintenance programs.

15. Improve understanding of the mobility-training requirements for low-vision persons and for the geriatric blind.

16. Provide greater understanding of the needs of the hearing-impaired blind person as related to his mobility and his hearing aid(s), if any.

17. Find solutions to the problems often engendered by the need for the blind trainee to be away from home, family, and job for a relatively long time during orientation and mobility training at a distant center.

18. Increase utilization of the "family program" where family members spend some time for orientation and learning, at VA's blind rehabilitation centers in the latter days of the veteran's stay.

19. Provide more data on the travel practices and environments of blinded veterans, and identification of those which encourage travel.

20. Improve and expand audio-visual informational vehicles, such as films about the many aspects of mobility maintained, developed, and distributed by an existing or new library.

21. Provide a national center for mobility research where new devices could be competently evaluated, where tests could be developed, where hardware and software could be considered, and where specifications and prescription criteria could be prepared.

22. Create a fourth blind rehabilitation center which is needed to accommodate the immense geographic distances in the United States.

CURRENT STATE OF THE ART

While current practices and devices allow a relatively small segment of the totally blind population to be spectacularly mobile, usually by em-

ploying commonplace methods, neither such methods nor the most sophisticated devices have yet made the bulk of blind people into travelers, able independently and with minimal stress to get around safely somewhat as a sighted person does.

Conventional mobility systems include the sighted guide, the cane (most effectively the long cane), and the dog guide. Several state-of-the-art systems will next be described.

The Laser Typhlocane has been developed by Bionic Instruments, Inc., of Bala Cynwyd, Pennsylvania, under a research contract funded by the VA. This electronic device in cane configuration embodies all the valuable capabilities of an ordinary cane; should its mechanism ever fail it can be used as an ordinary cane. It works using three very low-power gallium arsenide lasers which emit light in the infrared region at about 0.9 micron. One of the infrared beams is directed upward toward the space where the user's head will next pass as he walks forward. If there is an object which would strike the head, and sufficient energy is reflected from it to the optical mechanism of the cane, the cane will signal the user by emitting a high-pitched beep. The second beam is directed straight ahead. If an object is in this region, the cane, on receiving reflected energy from it, will signal the user before actual cane contact, either by a tactile stimulus on the finger, or by an optional medium-pitched sound coming from a small speaker in the crook of the cane. The third beam of infrared light is directed downward at the ground to a point about 3 ft. beyond the tip of the cane. If the ground is intact, there is no response from the cane. If, however, something interferes with the optical path of the transmitted, reflected, and received beam, a low-pitched tone will signal the user. Thus, if there is a curb 6 in. high or more, or a drop-off of this size or more, the beam will be interrupted in its path, and the user will receive early warning of the discontinuity in the terrain.

We hope that the improved models recently delivered to VA will be useful mobility tools for some of the blind. The new canes are expensive; they cost the Veterans Administration about $2,800 each in quantities of 35. Mr. J. M. Benjamin, Jr., president of Bionic Instruments, Inc., will give other details during his presentation at this meeting.

I should like to provide some data on the Binaural Sensory Aid for the Blind (Fig. 1), a product of Wormald-Vigilant, Ltd., of Christchurch, New Zealand. Many are aware of the mobility feats of blind bats, accomplished through the use of ultrasonic echo-ranging. This performance by bats suggests that similar means might be used by some blind men. We consider the Binaural Sensory Aid a supplement to cane or dog; when used alone it does not seem to provide the complete capability of a full mobility system. It is able to give its user early warning about things out ahead in the direction it faces. It gives an indication of the range and azimuth of such items, and sometimes even a clue as to their identity. It

achieves this by sending out from a transmitting transducer in a conventionally worn spectacle frame a broad beam of ultrasonic energy. Energy reflected from objects in the space reached by the sound is returned to the two receiving transducers in the eyeglass frame, and then converted into a sound which is conveyed to the user's ears through vented earpieces. It is important not to block ambient sound cues. During the last few years, a number of these binaural sensory aids, in the Mark I version, have been under study throughout the world. The manufacturer has gone ahead with plans to produce an improved version, the Mark II. This newer model, believed to be better engineered than its predecessor, is expected to be available in limited quantities at training courses for mobility professionals scheduled for September 1974.
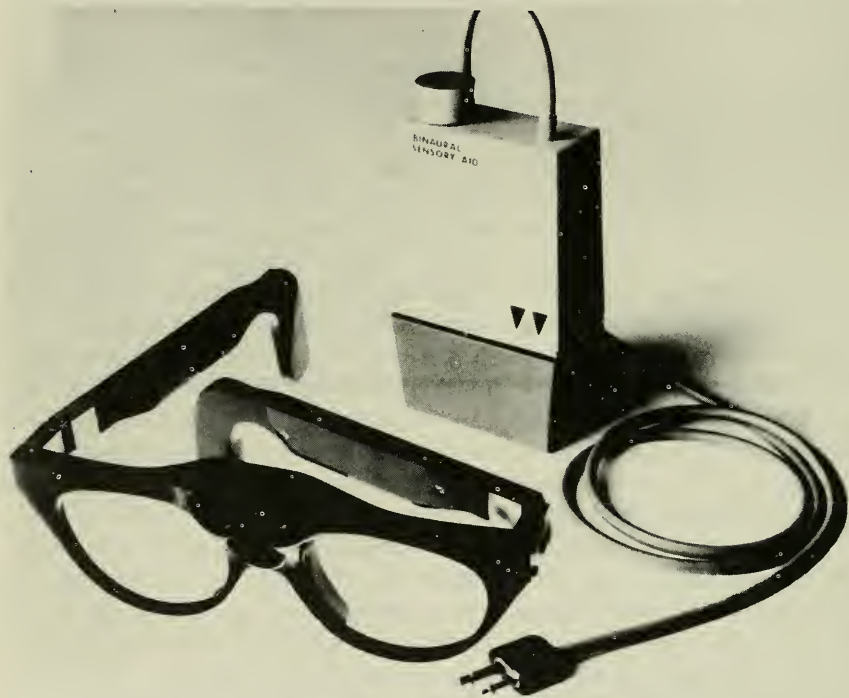
FIGURE 1.—Binaural Sensory Aid for the Blind, 1974.

In July of 1974 nine new model Lindsay Russell Pathsounders (Fig. 2) were received by VA for evaluative and clinical applications. The new units, generally similar to the original device, have several new features. The unsightly horns used to emit and receive the ultrasonic energy are no longer visible as projections from the unit. A two-signal tactile display now functions independently of or concurrently with the two-signal auditory display. This chest-worn device is silent until an obstacle comes

to within about 6 ft. A beeping sound, or vibration of the whole case, or both, signal this occurrence to the user. At about a 3-ft. range to the obstacle, the beeping increases in pitch and the tactile signal shifts to a vibrator incorporated into the neck strap to stimulate the back of the neck. This obstacle detecting device is to be used as an adjunct to a cane (or possibly a dog), and in some special applications, such as for a blind person confined to a wheelchair who may be able to get around independently in a comparatively safe, reasonably familiar area.

FIGURE 2.—The Lindsay Russell Path-sounder, 1974.

The Mowat Sonar Sensor (Fig. 3) conceived by Mr. Geoffrey Mowat of New Zealand, to be carried in the pocket until the user needs to probe the environment, gives an indication of range and azimuth to objects. It has a variable frequency vibration felt through the case, the frequency depending inversely on range. The direction in which it is pointed when echoes are received indicates azimuth.

The Mims Seeing Aid (Fig. 4) is another obstacle-detecting device which uses light emitting diodes to probe the environment in the direction of regard. If objects reflect some of this energy, the circuitry converts the return to audible form and signals the user through a small piece of plastic tubing placed loosely in the ear.
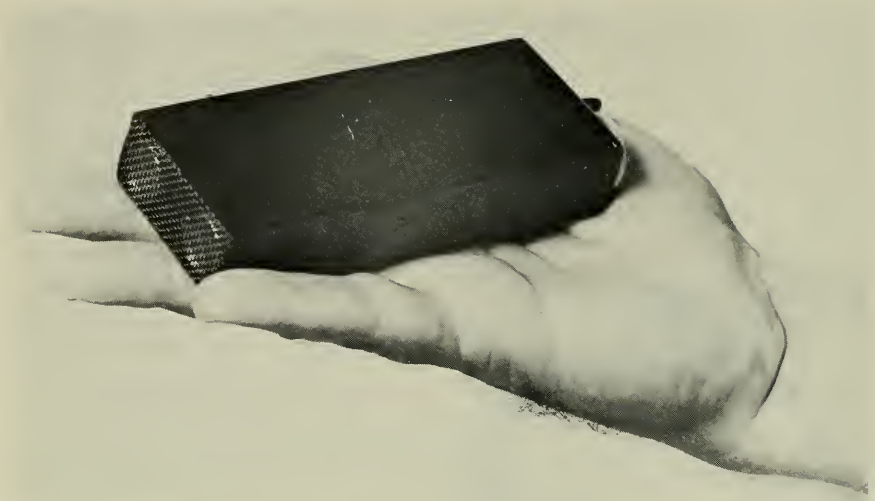
FIGURE 3.—Mowat Sonar Sensor, 1973.

FIGURE 4.—The Mims E-2 Eyeglass Seeing Aid, 1972.

While there are other electronic mobility aids, the ones mentioned above are those thought to be farthest along in their development, and best known in the United States. At the time of this writing, July 1974, none of these electronic devices could be said to be in widespread use among the blind population.

CURRENT STATE OF THE EFFORT
Amputation Surgery and Prosthetics

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Moderator

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The basic program on Current State of the Effort in amputation surgery and prosthetics follows a logical trend. The primary goal is to avoid amputation, if possible, by means of better measurement and management of vascular problems. Discussion of rational selection of levels leads to amputation surgery and healing. The possibilities of skeletal attachment of a prosthesis lead into better methods for fitting and major areas of prosthetics, including both external and internal prosthetic joints and control of external power.

This section on amputation surgery and prosthetics starts with Dr. Bok Y. Lee, of Castle Point VA Hospital, on Hemodynamic Evaluation in Selection of Amputation Levels. His goal is to prevent amputation, if possible, or at least to conserve stump length and joints as much as feasible.

The next speaker on the same general topic of rational selection of the amputation site, Dr. Wesley S. Moore, devotes special attention to Skin Blood Flow and Healing. He emphasizes the role of skin as distinct from arterial blood flow. Dr. Moore is a general and vascular surgeon from the VA Hospital at San Francisco.

This apparent trend toward prevention of amputation, more distal amputation, and successful wound healing is perhaps more than just a suspicion. Even a limited number of situations raises obvious suspicion of cause and effect. (One may recall Gilbert Chesterton's famous comment: One giraffe with his long neck is laughable, but if you can see two or more giraffes, that series begins looking like more than a coincidence!) Dr. Burgess, who has already spoken this morning, has pioneered and improved the immediate postoperative fitting in this country and has a very long series of cases involving that technique. He also has started research in a number of related areas, most recently concentrating on problems of wound healing in controlled environ-

ments using transparent chambers developed at the British Biomechanical Research and Development Unit at Roehampton, a suburb of London.

The daring thing in the early days of immediate postoperative fitting was to attempt dressing in the absence of this kind of transparent "socket." It took courage for Dr. Burgess, and others, to apply a completely opaque rigid plaster dressing and leave it on the fresh surgical wound for days at a time. Most people were sympathetic with any surgeon's passionate curiosity to know what was going on under the opaque plaster dressing. As a matter of fact, one of the other early experimenters in the cooperative research program developed what he thought was stump hygiene; he deliberately took off the cast every day to examine the stump and then quickly reapplied a new dressing. As it turned out, that seemingly conscientious and conservative method did not work well because of rapid development of edema, even in the few moments while the stump was free from support. Based both on extraordinary experience with the rigid plaster dressing and on recent experiments, Dr. Burgess will discuss Wound Healing.

Unfortunately, Dr. Sarmiento has been plagued with problems. His associate who was supposed to have come to Chicago developed scarlet fever. Dr. Sarmiento said that he has not heard of the disease since he was a medical student himself and did not realize that anybody got scarlet fever anymore! Two other colleagues were unable to come because they are deeply involved in giving a course. Then Dr. Sarmiento, who was here this morning, was called back in an emergency. However, Dr. Edward Peizer, of VAPC, will replace Dr. Sarmiento to describe the work on complicated prosthetics fitting problems at University of Miami.

Mr. Leon Bennett, an engineer from New York University, has been involved with the artificial limb program since 1947, originally working with Mr. Renato Contini's group which was involved for many years in the evaluation of devices. Recently Mr. Bennett has been working part time with Dr. Fishman in the prosthetics education program and in the evaluation of devices for the Children's Bureau and the Maternal and Child Health program. He has also worked part time with VA support on mathematical, experimental, and model studies of stresses in flesh near a load. He is concerned particularly with the transfer of load from the socket of an artificial limb (or presumably the cushion of a wheelchair or the cuff of a brace) to the flesh. He has produced a number of interesting analyses of the distributions of compression and shear at and near a socket brim. Some of the results showing stresses in flesh *proximal* to the brim are not always self-evident to the layman.

This is an area of interesting interplay among theory, simple experiment, and clinical experiment, on a problem that has long been serious.

As is well known, above-knee amputees often have developed cysts in the adductor region. In the Barnes and Levy issue of Artificial Limbs, in 1956, such cysts were described as part of Dr. Levy's discussion of a variety of dermatological problems of amputees. (This paper is reproduced in the book *Selected Articles from Artificial Limbs.*) In the days before total-contact sockets, problems were typically just above the brim of the medial aspect of above-knee sockets, in the popliteal space above the brim of below-knee sockets, or at the end of the stump. The PTB below-knee and total contact above-knee sockets were later developed. Originally, when many amputees literally flinched at the thought of anything touching the end of the stump, one of the major goals of these sockets was to provide counterpressure to prevent terminal edema, thus helping to clear up problems at the end of the stump, shown clearly by studies performed at University of California. Thereby distal problems have been sufficiently solved for many years, but occasional skin problems above the brim still persist. In experimenting with current difficult cases, Mr. Bennett is receiving cooperation from the staff at Castle Point VA Hospital who are providing medical supervision and the recording of clinical problem cases; also, he will work with the VA Prosthetics Center. One may hope that ultimately some improvements will be possible in this second half of the dermatological problems, just as total-contact largely solved the edema problem.

Another way in which one might overcome problems in fitting of prostheses would be to "fit" to the patient, in the operating room at the time of amputation, a skeletal attachment protruding through the skin. In this way an external prosthesis could be attached through a quick disconnect. (Some sort of skeletal attachment to the patient might also be made at the time of the operation, initially buried but then, with a later procedure, exposed by coming through the skin.) This concept of skeletal attachment, of course, gets out of the frying pan of dermatological problems into the fire of much more serious biological problems. Surgeons and others with any biological training typically "know" that this intrusion through the integument will never work; it has been routinely condemned for many years. Nevertheless, there were experiments performed in Germany and in the United States during World War II and Dr. John O. Esslinger reported his animal experiments in this Bulletin (BPR 10-1 through 10-13). A few brave souls still retain an interest in the possibility of coming through the skin without supposed inevitable infection or inevitable biological rejection of the device. One such person is Dr. C. William Hall, a vascular surgeon, who originally was faced with the problem of trying to bring a power supply for an artificial heart through the chest wall. Later he perceived various concepts for use of such devices, including artificial limbs. He has a small VA-supported project at Southwest Research Institute.

At this point it should be noted that each participant has been given the opportunity to sign up for an appropriate workshop. Mr. Everett Cortright, Prosthetics Research Specialist from Dr. Newcomb's office in Washington, made the arrangements.

The next speaker, Mr. Hans A. Mauch, is a well known pioneer of the artificial limb program, who started working with Dr. Ulrich Henschke, and M.D. and a Ph.D. in physics, while both of them were still in Germany. We learned of their ideas when a team from the Army Surgeon General's Office visited Germany in spring 1946. Eventually they came to this country and worked with the Air Force for a number of years. Mr. Mauch initially worked on hydraulic knee joints, and then on ankles for artificial legs, as we shall hear today. Eventually he became involved as well with reading machines for the blind, as we shall hear from him and his associate, Mr. Smith, tomorrow. Mr. Mauch now has his own laboratory in Dayton, Ohio.

The next speaker is Professor Charles W. Radcliffe of the University of California. Another pioneer in the limb program, he became involved when he worked for Narmco, a subcontractor to the National Academy of Sciences, in 1946. Later he went to the University of California, which started to become active in the limb program in September of 1945. The University of California project illustrates the combination of fundamental studies in locomotion with subsequent design and development of specific devices reaching widespread clinical use. Long ago, Professor Radcliffe developed biomechanical principles for fitting and alignment of artificial legs at all levels, from the Syme to the hip disarticulation. He also developed a series of adjustable legs and copying jigs to facilitate application of these principles. He has been instrumental in development of the SACH foot, the PTB high-brim and TCS sockets, and multiple-bar linkages for knees.

Dr. Jacquelin Perry of Rancho Los Amigos is working on clinical gait analysis. She intends to develop a simple, inexpensive method using a hand-held calculator which does not require anything near the level of computer that Professor Radcliffe and Dr. Lamoreux worked with at University of California. Obviously there are great needs for quick, practical, but accurate analysis of gait of patients with any of a wide variety of clinical conditions. Objective measures of improvement after treatment would be very helpful.

There has been for the past year or so a VA project at Case Western Reserve University (CWRU) by Dr. Albert Burstein, a bioengineer. Working under him are Drs. Victor Frankel, an orthopedic surgeon, and Dr. E. Byron Marsolais, an orthopedic surgeon with a Ph.D. in engineering. There is close cooperation between CWRU, Highland View Hospital, and VA Hospital, Cleveland. The project deals with in-vivo telemetering of the stresses in surgically implanted artificial knee

prostheses. This is becoming increasingly popular as a method of replacing the arthritic or otherwise damaged knee, by analogy of the total hip operation which has been so successful in recent years. The problem is to measure the loads within the device itself and telemeter information out through the intact skin, recording the subject during gait and while performing various activities. The CWRU group made some preliminary experiments with the telemetering hip nail, which they already had developed in order to train their nurses and others involved. Tests with their aluminum mockup verified that the strain gages are able to measure loads in all three directions within the knee joint. Now they plan to build others, probably with surgical grade stainless steel, which they expect will transmit the radio waves. The entire outer shell of the stainless steel serves as the antenna for the telemetering of the strain-gage information from the gages inside the joint; in this way they will be able to measure vertical and shear loading on the knee joint as the patient moves.

Northwestern University in addition to serving as host for this Conference, has been involved for many years in a VA-supported interdisciplinary project on artificial limbs, particularly to aid geriatric and severely handicapped amputees. The project has been provided with ample clinical opportunities by physical location in the Rehabilitation Institute of Chicago, proximity to the VA Research Hospital, association with Dr. Thompson who conducts a VA clinic team, referrals from various other clinics, and for some years a close relationship with the Michigan Crippled Children's Commission program. Dr. Childress originally was especially interested in myoelectric control, but he and Mr. Billock then extended their efforts to develop a self-suspended, self-contained artificial arm for the below-elbow amputee. One might suggest that myoelectric control first fascinates many engineers but ultimately serves as bait to lure them into studying the *real* problems of fitting.

The next speaker, Dr. John Lyman of the University of California at Los Angeles, will discuss voluntary and adaptive control on upper-limb powered prostheses. Beginning in 1946, the UCLA project is one of the early pioneers in the prosthetics program. Dr. Lyman has been involved throughout most of its history, originally working with Dr. Craig Taylor in measuring arm and hand motions, much the same as the Berkeley group measured locomotion. Dr. Lyman has long been active in evaluating the various attempts to provide external power for artificial arms. He and his associates have studied the basic problems of control in an attempt to reduce the demands made upon the amputee.

Dr. Graupe, from Colorado State College at Fort Collins, Colorado, is particularly interested in the mathematical principles of signal recognition in separation of signals from noise. He is applying these concepts to

detection of myoelectric signals. He and his students have also built a toe-controlled arm with multiple motions which can be controlled through a logic system, substantially extending the Alderson toe-controlled arm.

Dr. Schmeisser, of Johns Hopkins Medical School, and Mr. Seamone, of the Johns Hopkins Applied Physics Laboratory, have been working together for some years on the development of a different approach to power-driven prostheses and orthoses. The basic approach involves a versatile winch-like drive for a Bowden cable, a quiet and relatively slow torque motor (rather than the usual high speed motor and large ratio reduction gear), and an assortment of controls, including myoelectric, small skin motion, and even clicking of teeth.

HEMODYNAMIC EVALUATION IN SELECTION OF AMPUTATION LEVEL

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INTRODUCTION

Although the amputee and his remaining limb present many interesting and challenging problems, no detailed study exists of the progression of vascular changes in the remaining limb of the amputee. Goldner (1) in 1960 stated that the second leg of the unilateral diabetic amputee shares the fate of the first rather often and relatively soon. A somewhat similar fate can be assumed for the patient with arteriosclerotic occlusive disease who may or may not have diabetes.

Since a remaining limb of an amputee or a contralateral limb of a vascular patient will eventually manifest vascular problems, the limb or limbs should be followed and assessed until a condition is presented for an initial or second amputation.

Peripheral vascular disease in its most common form represents an insidious progressive process of arterial involvement. The exact etiology of the disease is not known. It is, however, characterized by a gradual deposition of fibrous plaques in the intima of the major arteries. The deposits thicken reducing the flow of blood through the vessels. Eventually the vessel or vessels may become stenosed with a resultant inadequate blood supply to dependent tissues, when critical stenosis is reached. Tissue function is compromised and gangrene will undoubtedly occur. As part of the search for clues and predictors related to the nature of progressive vascular changes, we are studying pulsatile blood flow waveforms (2,3) in the remaining limb of both recent and older amputees, and bilaterally in patients without amputation.

METHODS

Because of the progressive nature of peripheral vascular disease, we believe that vascular test procedures, and especially the noninvasive diagnostic and screening techniques, help to identify early changes in the vasculature and thus lead to prompt remedial action.

Vascular test procedures play an important role in: 1. determining the

degree of vascular involvement, 2. locating the possible site or sites of obstruction, 3. assessing success or failure of reconstructive vascular procedures, 4. determining the level for amputation of a limb, 5. assessing efficacy of treatment and therapy, and 6. monitoring progression of disease. It is essential that all known or suspected vascular patients have a periodic evaluation of their vascular status.

At Castle Point VAH, the Vascular Clinic has become the focal area for all activities related to preoperative and postoperative evaluations and followup testing for the vascular patient.

After an initial series of noninvasive vascular tests, all patients with indications for surgical procedures are scheduled for angiography. Patients who have received their initial series of noninvasive vascular tests are included in a vascular registry and are scheduled for continued screening tests at least three times a year. Three screening tests used routinely are: 1. Pressure Gradient Evaluation, 2. Ultrasonic Doppler Blood Velocity Analysis, and 3. Claudication Evaluation.

Following angiography, a patient may be recommended for further testing which may then be followed by lumbar sympathectomy and/or reconstructive surgery and further test procedures. Currently, in our vascular registry there are over 500 patients with varying degrees of peripheral vascular disease who are being monitored on a regular basis using noninvasive test procedures. The prevention of and the reduction of limb amputation due to peripheral vascular disease require a total program of continuing noninvasive vascular testing which is quantified wherever feasible.

Measurement techniques for the evaluation of peripheral vascular disease fall into two broad categories, i.e., the direct and the indirect. Once a patient is referred to the clinic all screening tests are initiated, and if surgery is contemplated direct testing techniques are considered. Direct methods involve invasive procedures and therefore their use is somewhat restricted. In seriously involved vascular disorders and during vascular surgery, angiography and invasive electromagnetic flowmetry are used. The primary burden of a vascular testing technique, which is to be used repeatedly, is that it must be noninvasive in character. However, whether direct or indirect, correlation of test results with the patient's clinical course is extremely important.

1. Square Wave Electromagnetic Flowmetry

Over a period of 10 years our clinical application of the square wave electromagnetic flowmeter (4,5) has enabled us to evaluate mean flow rates and pulsatile blood flow patterns in the peripheral arterial system of patients with peripheral vascular disease. The squarewave EMF provides an immediate, quantitative, accurate method of measuring mean blood flow and pulsatile blood flow intraoperatively before and after

reconstructive surgery and before the patient is released from the operating room. The invasive EMF provides a means for measurement of blood flow in surgically exposed but intact arteries and veins. A flow probe produces a magnetic field across the intact vessel. Blood flow through the field generates an electrical current proportional to the quantity of the blood. A typical pulsatile arterial waveform (Fig. 1) will show a rapid acceleration phase, a slower deceleration phase, and a reverse flow component depending upon the vessel. Mean blood flow appears as a digital readout on the flowmeter.

PULSATILE ARTERIAL WAVEFORM

Peak amplitude

Acceleration
(ml/min/ms)

Deceleration
(ml/min/ms)

Accel. Decel.
duration duration

Zero flow

Pulse duration
(ms)

Time Interval

Mean flow (ml/min) = numerical readout on the flowmeter

Elasticity index (Ei) = $\dfrac{\text{Deceleration duration (Dd)}}{\text{Pulse duration (Pd)}}$

A typical pulsatile flow pattern will show a rapid acceleration phase, a slower deceleration phase, and a reverse flow component depending upon the vessel. Measurements of the descriptors of pulsatile flow are compared for the vessel proximal to the graft, for the graft, and for the vessel distal to the graft.

FIGURE 1.—A typical pulsatile arterial waveform.

To illustrate the use of this technique, the following study is presented. A 46-year-old man experienced claudication in his left leg and coldness of his left foot 3 days after a fall in which he struck his left buttock and hip. Marked ischemia of the leg and foot with superficial gangrene of the left great toe soon became evident and femoral, pop-

liteal, and pedal pulses were completely absent on this side. A translumbar aortogram showed occlusion of the left common iliac artery. Thromboendarterectomy of the left common iliac artery, left lumbar sympathectomy, and electromagnetic flowmetry were done. The pain in the foot disappeared, the foot and leg became warm, and pulsations were restored to the left femoral and popliteal arteries. The superficial gangrene disappeared and the patient remained asymptomatic 7 years later. Quantification of the flow patterns (Fig. 2) for the left external iliac artery showed changes in the descriptors of the waveform after endarterectomy and lumbar sympathectomy. Mean blood flow increased from 94 ml. per min. to 252 ml. per min after thromboendarterectomy, and further increase to 394 ml. per min. after lumbar sympathectomy. Prior to thromboendarterectomy, the flow tracing for the left external iliac artery showed low amplitude, prolonged and irregular flow acceleration, and deceleration patterns. The irregular flow trace indicated proximal as well as distal occlusion. Immediately following thromboendarterectomy, flow acceleration and peak amplitude increased with the pattern showing a sharply rising peak and relatively smooth trace. The deceleration portion of the trace continued to be prolonged indicating distal peripheral arteriosclerotic involvement. After lumbar sympathectomy the flow trace showed further improvement in these parameters.
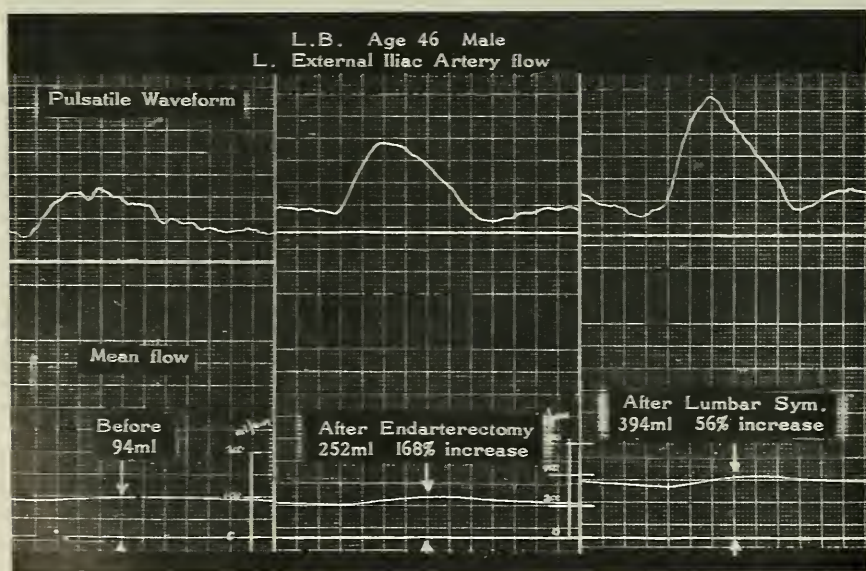
FIGURE 2.—Pulsatile waveforms for left external iliac artery before and after thromboendarterectomy and lumbar sympathectomy.

There are several noninvasive techniques now in use in our clinic to determine peripheral vascular involvement: 1. palpation of arterial

pulses, 2. peripheral blood pressure determination, 3. limb temperature profile, 4. Ultrasonic Doppler Flowmetry, 5. Electrical Impedance Plethysmography, 6. Noninvasive Electromagnetic Flowmetry, and 7. Peripheral Pulse Timing. The initial vascular screening techniques are designed to rapidly and quantifiably determine the adequacy of the peripheral circulation. Systolic blood pressures are determined bilaterally by an inflatable cuff and ultrasound detection system for the upper arm, forearm, thigh, and ankle at rest and after a period of exercise. Ultrasonic Doppler Flowmetry is used to ascertain the relative quality of arterial flow velocity at various locations on the extremities. The claudication evaluation determines the time and distance of the onset of leg pain after walking. Tests of programed exercise (extension/flexion) are employed to yield a quantifiable and repeatable value for claudication.

2. Blood Velocity Detection or Doppler Ultrasonic Flowmetry

Blood velocity detection or Doppler Ultrasonic Flowmetry (6,7) is particularly useful for detecting blood flow in severely diseased vessels. Flow can be detected when peripheral pulses are no longer palpable. In principle the device utilizes ultrasound energy which is focused into the moving blood stream. A portion of the transmitted energy is reflected from the moving blood. The reflected frequency varies depending upon the blood flow velocity; a signal representing pulsatile blood flow is obtained. The directional Doppler determines forward and backward blood flow components.

3. Electrical Impedance Plethysmography

When screening tests confirm some degree of vascular involvement, a more detailed noninvasive evaluation is done. A very important technique in this category is electrical impedance plethysmography (8,9). This technique utilizes the concept of a limb segment as a volume conductor of high frequency electrical current. Measurement of impedance fluctuations can be interpreted as volume changes due to arterial pulsations. Quantification of the amount and quality of these pulsations can be related to the status of the vasculature.

Analysis of the electrical impedance waveform (Fig. 3) for eight waveform parameters is obtained by means of a computer. Analog data is fed directly to the computer (PDP-8) or else recorded on magnetic tape for subsequent computer analysis. Impedance measurements are obtained at several segmental locations before and after exercise. A 52-year-old man with bilateral arteriosclerotic involvement complained of pain while walking; however, the pain was greater in the right leg. During his clinical evaluation, pressure gradients were determined (wrist-ankle) bilaterally with no gradient present at rest. Systolic blood

ANALYSIS OF ELECTRICAL IMPEDANCE WAVEFORM

Acceleration	Ac	Ohm/sec
Acceleration Time	AcT	Msec
Deceleration	Dc	Ohm/sec
Deceleration Time	DcT	Msec
Peak Height	PH	Mohm
Pulse Duration	PuD	Msec
Index	I	
Area	A	Ohm-msec

Index = Dct/(Act+Dct)

PuD = AcT + DcT
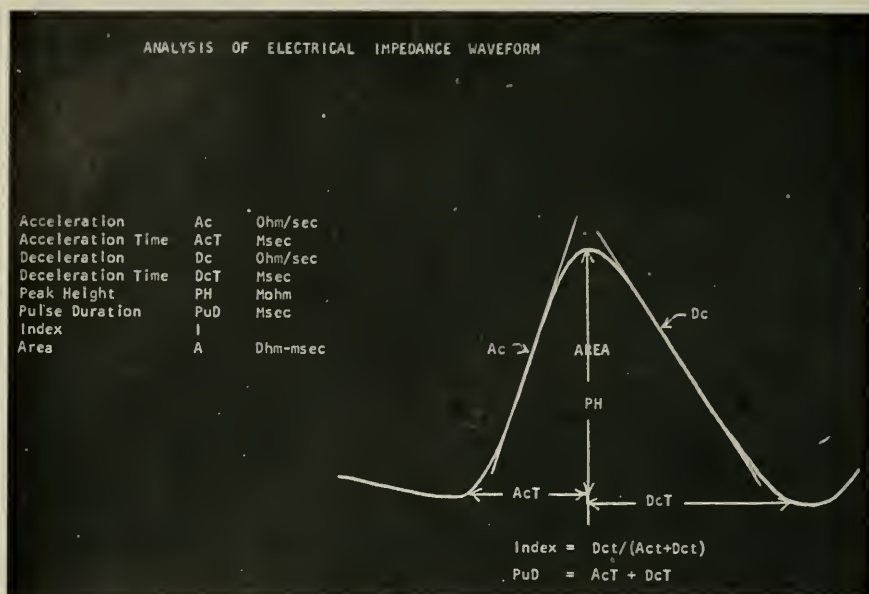
FIGURE 3.—Analysis of Electrical Impedance Waveform.

pressure was 148 mm.Hg. in ankles and wrists at rest. The impedance plethysmographic wave forms for the thigh to ankle segment bilaterally showed a different pattern for the right segment as compared to the left segment indicating greater involvement in the right segment (Fig. 4). This is indicated in the printout especially for acceleration, acceleration time, and peak amplitude with increased acceleration (2.35) and a peak height (126.3) and decreased deceleration time (90) for the left leg as compared to right acceleration (1.93) and peak height (116.8). Further changes in the waveform were evident immediately following exercise. The computerized quantification of the impedance waveform pattern reflects the apparent visual changes.

4. Noninvasive Electromagnetic Flowmetry

During the past 18 months, the Surgical Research Service has been using a new noninvasive electromagnetic blood flowmeter (10) which measures blood flow in peripheral vessels (Fig. 5).

In principle, a moving conductive fluid (blood) generates an electrical potential perpendicular to both the magnetic field and the direction of flow. The magnetic field is generated by a large permanent magnet exterior to the body. Skin electrodes detect voltages which are proportional to the quantity of the flowing blood. Data is processed to disting-
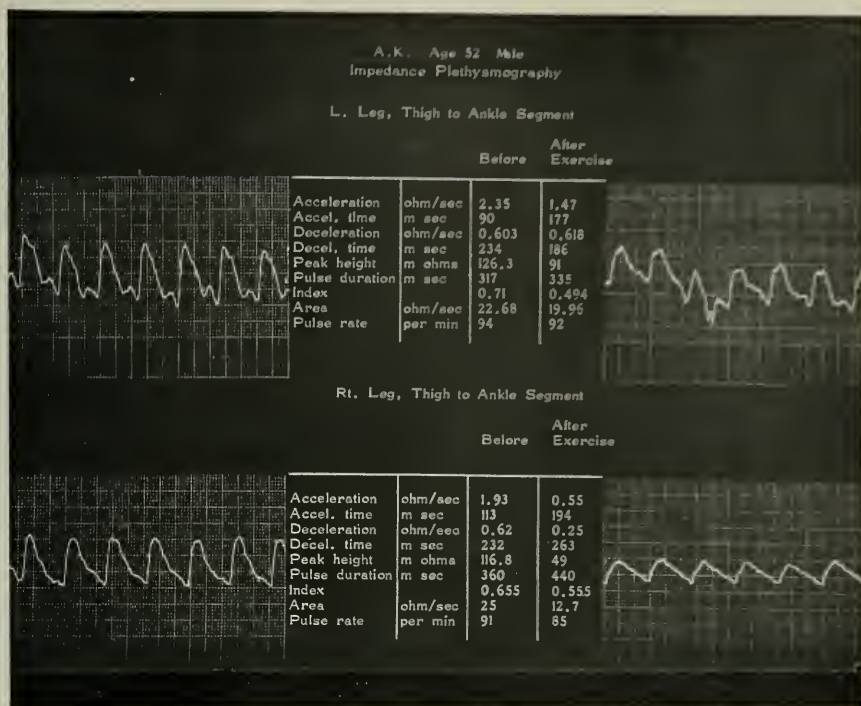
FIGURE 4.—Electrical Impedance Plethysmography.

uish between the blood flow signal and background noise due to ECG and myoelectric potential.

A 65-year-old man complained of claudication of several years duration with greater pain in the left leg than in the right. A bilateral femoral arteriogram showed bilateral arteriosclerotic disease. The involvement was limited to the popliteal arteries and was particularly severe in the left posterior tibial artery. Noninvasive EMF flow patterns were obtained with electrodes positioned at four sites each 2 in. apart over the left popliteal artery (Fig. 6). Evidence of the involvement was seen by disappearance of pulsatile flow in the area of the left posterior tibial artery (D). This confirmed the arteriographic findings (Fig. 7). Good correlation has been obtained by comparing the pre- and post-reconstructive vascular surgery blood flows with measurements obtained during the operation using the invasive electromagnetic flowmeter.
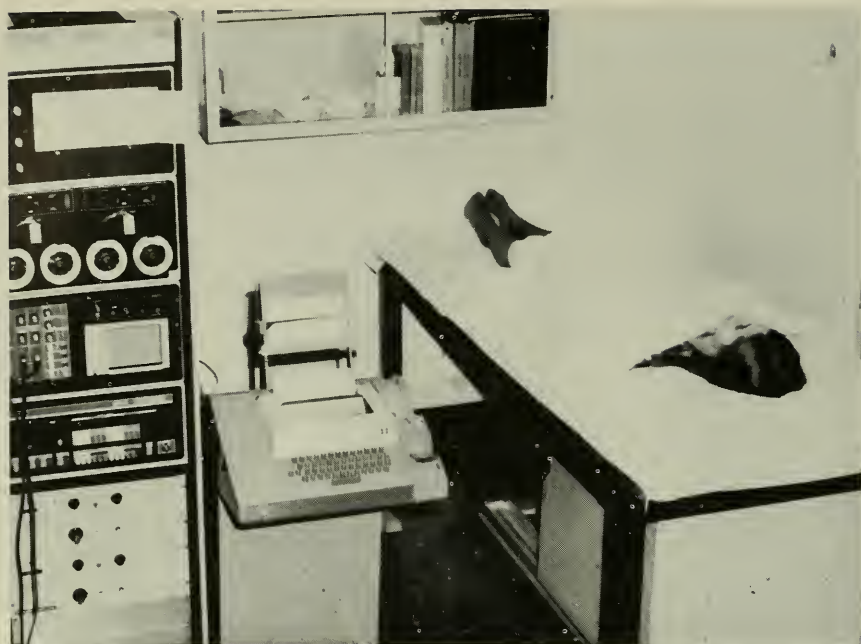
FIGURE 5.—Noninvasive Electromagnetic Flowmeter. Legend: Digital Equipment Corp. PDP-8 Computer: Teletype for input and output located between patient and computer. Patient rests on special table. Magnet rests on track beneath the table.

5. Thermistor-Thermometry and Liquid Crystal Thermography

The observation of skin surface temperature of the limbs provides very useful information with respect to blood flow (11,12). The surface temperature of a limb approaches that of its environment when circulation is arrested. The thermistor-thermometer is a useful device for detecting surface temperature. Thermistors are taped to the skin surface at different sites and a direct temperature readout is obtained. All temperatures are recorded with respect to room temperature and forehead temperature. Liquid crystal thermography is a simple, accurate, reproducible, and practical method for detecting and monitoring surface temperature of ischemic limbs. Liquid crystal thermography and thermistor-thermometry determinations are correlated with blood flowmetry measurements before and after surgical procedures. This technique is especially useful in determining level for amputation.

A 52-year-old man with known peripheral arterial occlusive disease was readmitted to Castle Point in 1970. Peripheral vascular disease had been diagnosed in 1964. In 1966 a bilateral lumbar sympathectomy and a right above-knee amputation because of gangrene were done. He was rehospitalized in 1970 with a complaint of redness, swelling, and pain in

the left foot. Exploration of the left femoral artery and intraoperative arteriography were done. None of the major branches of the femoral artery was visualized and only a streak of dye could be seen in the posterior tibial artery. A Dacron graft was inserted. The patient showed some improvement and gangrene was localized to the big toe. Postoperatively the pain in the foot continued and amputation was considered. Prior to amputation, skin surface temperatures were determined using liquid crystal tape with a resultant decision for a Syme amputation. The patient did well postoperatively with good healing of the wound. He was given therapy for prosthesis walking, and 7 months postamputation the patient left the hospital in satisfactory condition. Plans were made to follow him as an outpatient but soon after discharge the patient died of a heart attack.
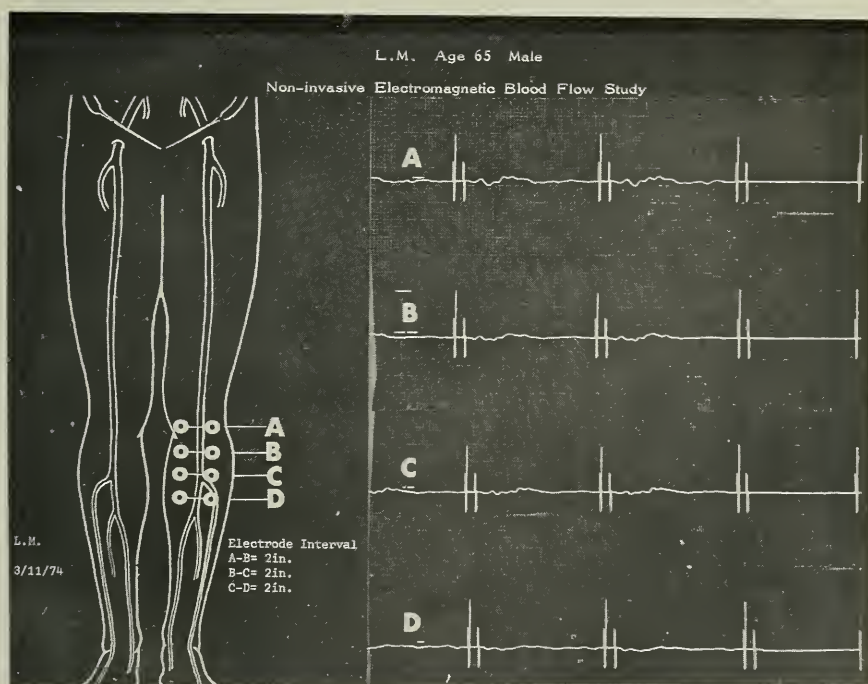
FIGURE 6.—Noninvasive Electromagnetic Blood Flow Study.
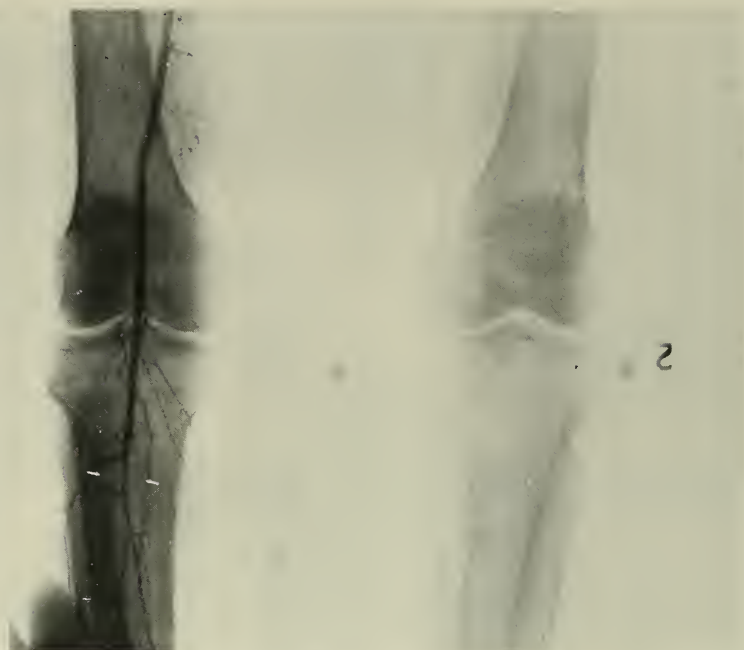
FIGURE 7.—Arteriogram—site of obstruction.

6. Peripheral Pulse Transmission Time Analysis (Fig. 8)

Pulse waves are detected using Photoplethysmograph detectors located in several peripheral sites. Simultaneous bilateral peripheral pulse transmission times are determined relative to the R wave of the electrocardiogram. The pulse wave velocity and transmission time is dependent on cardiovascular properties and is modified by arteriosclerosis and vascular stenoses. Peripheral pulsations were obtained bilaterally for a 44-year-old man who had sustained a traumatic right below-knee amputation 21 years prior to the test. He had been fitted with a prosthesis but had now begun to manifest signs of vascular disease in the stump. Peripheral pulsations were compared with respect to the onset of the R-wave of the ECG for the right and left radial and right and left femoral arteries (Fig. 9). Identical times were obtained for the right and left radial arteries and the left femoral artery (150 ms.). However, transmission time in the diseased right femoral artery (240 ms.) was increased by 90 ms. compared to the time for the left femoral artery. Angiography confirmed this finding and showed occlusion of the right iliac artery.

FIGURE 8.—Peripheral Pulse Transmission Time.
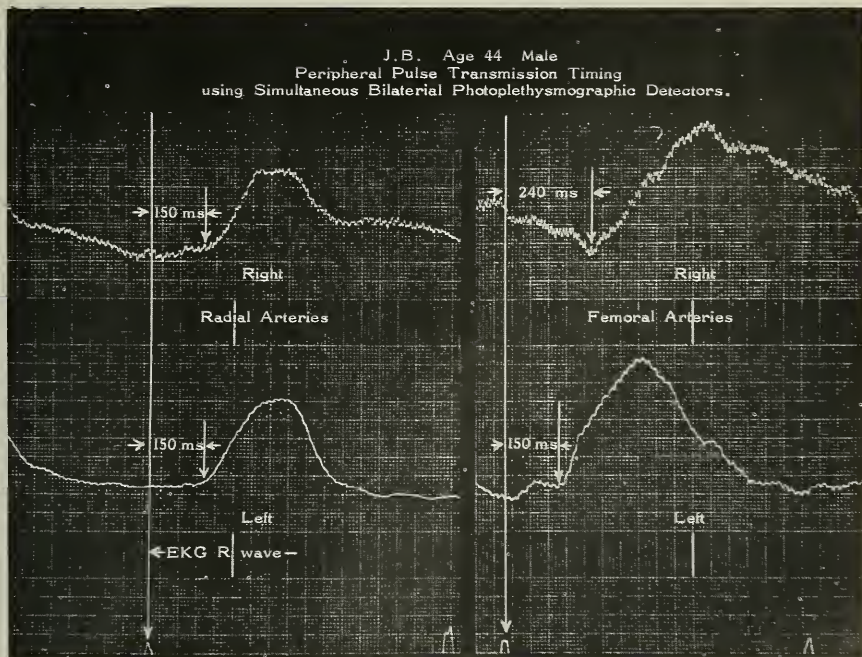
FIGURE 9.—Peripheral Pulse Transmission Time Study.

REPRESENTATIVE CASE STUDIES

1. Development of Arteriosclerotic Disease in Stump of Amputated Limb

A 43-year-old veteran, who served in the U.S. Army from 1952 to 1954, sustained a traumatic below-knee amputation during this period of service and before leaving the service he was fitted with a prosthesis (thigh corset type) which was held in place with straps that were somewhat constrictive. When evaluated in our clinic, the patient stated that he had been able to walk with this prosthesis for 18 years. However, in 1959, he had been treated for cellulitis of the lateral aspect of the right below-knee amputation stump and again in 1972 he was treated for stump pain secondary to a bony spur on the right leg at which time revision of the amputation stump was also done. From November 1972 to January 1973 he had visited the outpatient prosthetic clinic and was fitted with a new prosthesis. On May 13, 1973, he complained that he could not tolerate the socket, and an open ulcer had appeared in the stump scar. The ulcer was treated and appeared to be healing. Numerous visits were made to prosthetic and orthopedic clinics for adjustments to the prosthesis. By July 1973, the patient had not been able to wear his prosthesis for 9 weeks and the pain he was experiencing kept him awake at night. By August 1973, at another clinic, it was found that the femoral and popliteal pulses were absent on the right side. The skin temperature of the amputation stump was reduced and the distal 2 in. were especially cold. Diagnosis was recorded as below-knee amputation, right, with peripheral vascular disease causing an ischemic ulcer on the end of the stump. The patient was advised to discard the prosthesis temporarily, to stop smoking, to take supplemental vitamins, and to do Buerger's exercises. By November 1973, a crust had formed on the lesion and it was suggested that the patient have the prosthesis checked. In April 1974, the patient found he still could not wear the leg because the stump became irritated after 1 hour when wearing the prosthesis. At this time the patient was referred to our clinic. Decreased circulation to the stump scar was evidenced by the bluish tinge of the tissue. A temperature study confirmed the decreased skin temperature of the thigh. A bilateral arteriogram showed severe arteriosclerotic involvement of the right iliac and femoral arteries. The left side was found essentially normal. A right lumbar sympathectomy was done with resultant improvement in the skin temperature of the stump and color of the scar tissue and disappearance of the pain. The patient has now resumed use of his prosthesis.

This case study emphasizes the particular need to evaluate the status of the vasculature of the amputation stump as well as of the remaining limb. Perhaps all too frequently the prosthetic device receives the greater attention and concern. In the case of this patient, because of the total absence of involvement of the remaining limb, the constrictive nature of

the prosthesis worn by this patient might be considered as a contributing factor to the development of arteriosclerosis in the amputation stump.

2. Prevention of Amputation (13,14)

At the age of 63 years, a known diabetic with generalized arteriosclerosis was admitted because of a painful infection and gangrene of the right foot of 1-month duration. Prior to this admission to Castle Point VAH, the patient had been hospitalized at another institution because of impending diabetic coma and the gangrene of the fourth and fifth toes of the right foot. The gangrene of the toes did not improve with conservative treatment, and amputation of the foot was advised. The patient refused this choice and was brought to Castle Point for further treatment. On admission, examination found gangrene of the fourth and fifth toes of the right foot (Fig. 10) with a denuded ulcer at the dorsum of the foot through the metatarsal area. One week following his admission, a right lumbar sympathectomy was done. The postoperative course was uneventful. The right foot was soaked daily, and 3 months postoperatively a small skin graft was applied. Gradually the wound healed (Fig. 11), and 6 months after the lumbar sympathectomy the patient was discharged to be followed in the clinic. Five years post right lumbar sympathectomy the patient continues to have good skin surface temperatures for the right foot; there is no pain and no gangrene. He ambulates well and is totally self-sufficient.

A 44-year-old diabetic male was hospitalized with bilateral plantar calluses and an ulcer on the right foot. At this time with appropriate control of the patient's diabetes and conservative treatment of the calluses and ulcer he was discharged to be followed in the clinic where he visited sporadically for a period of 1 year. Subsequently, he was readmitted for an ulcerating lesion of the planter surface of the left foot; his diabetes was again uncontrolled. This time a bilateral femoral arterio-

FIGURE 10.—Gangrene of 4th and 5th toes before lumbar sympathectomy.

FIGURE 11.—Fourth and 5th toes after lumbar sympathectomy.

gram showed well opacified femoral arteries and good run-off to the ankles. Following 3 months of conservative treatment, the patient consented to a left lumbar sympathectomy following which, the ulcerating lesion of the left foot showed decided improvement; however, he refused a right lumbar sympathectomy. Approximately 1 year later he was rehospitalized with impending gangrene of the right great toe. He consented to the right lumbar sympathectomy and the impending gangrene disappeared. Further treatment has been necessary for the right foot, i.e., pinch graft with slow but steady improvement. Following right lumbar sympathectomy and with strict dietary control and administration of insulin, the patient's chances of retaining full use of his feet are good.

A translumbar aortogram of an 85-year-old man showed complete blockage of the right aorto-iliac femoro-popliteal system. The patient complained of rest pain and impending gangrene was evident in the right lower limb. Initially a right lumbar sympathectomy was done, but no change in the skin temperature of the right foot was evident. This lack of improvement in surface temperature following the sympathectomy was attributed to the fact that the circulation to the limb was blocked. Thromboendarterectomy of the right profunda femoris artery and insertion of an axillo-femoral bypass were done (Fig. 12). Good pulsatile blood flow was observed in the vessels of the limb. The foot became warm and the higher temperature of the foot as compared to the thigh termperature indicated the effect of the lumbar sympathectomy. The impending gangrene and rest pain disappeared. The combined use
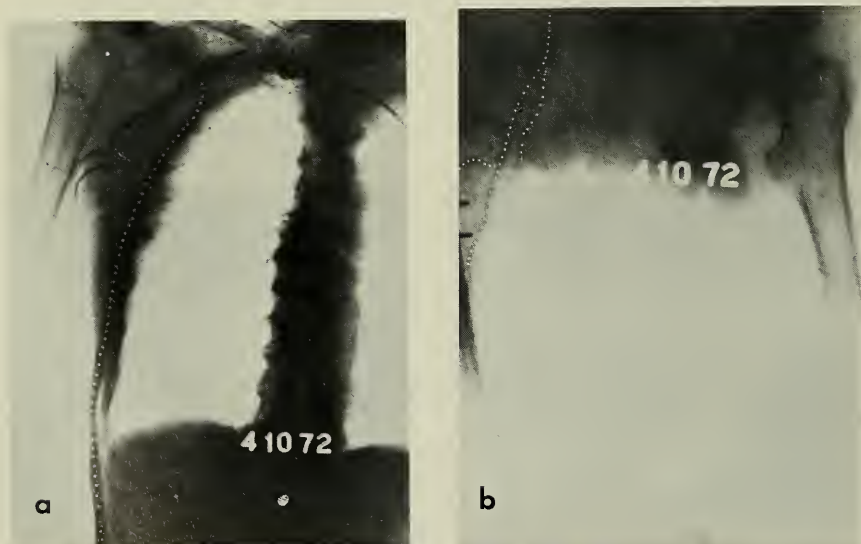
FIGURE 12.—Axillo-femoral bypass graft.

of lumbar sympathectomy plus the axillo-femoral bypass graft which was inserted subcutaneously prevented an impending amputation for this geriatric patient and provided him with the viable limb.

A 75-year-old male with diabetes and peripheral arterial occlusive disease complained of intermittent claudication in the right lower limb. Since an arteriogram showed blockage of the right femoral artery, a right lumbar sympathectomy and right femoral endarterectomy were done. Two years later as the disease progressed, the patient returned with gangrene of the right second toe (Fig. 13). A translumbar aortogram showed unilateral occlusive disease with severe involvement for the right lower limbs. Because of the patient's age, presence of ASHD, and diabetes, a subcutaneous crossover femoro-femoral graft was selected (Fig. 14) for this patient. The gangrene was arrested following insertion of the graft, and the toe gradually regained a normal appearance (Fig. 15).

FIGURE 13.—Gangrene of right big toe before cross-over graft.

FIGURE 14.—Cross-over femoro-femoral graft.

FIGURE 15.—Right big toe after cross-over graft.

Several important aspects of patient care should be emphasized; i.e., followup and regularly scheduled visits to the vascular clinic are essential. The patient's interest in his well-being must be maintained, whereas the physician is afforded the advantage of correlating clinic visits and observations with prior treatment and evaluation. At the same time the progressive changes are more easily detected and earlier corrective or palliative measures can be instituted. Once an amputation is done, continued evaluation of the remaining limb is essential in order to maintain this limb.

3. Level of Amputation

Because of years of nonattendance in the vascular clinic, a 79-year-old male was eventually hospitalized for an infected big toe of the left foot. At this time ASHD and PVD with segmental occlusion of the left superficial femoral artery were determined. A femoro-popliteal bypass graft and excision of the left great toe nail were done. The patient did well for 3 weeks, when pain and infection in the toe returned. At this time amputation was considered. Prior to the amputation, electrical impedance plethysmography and temperature studies were done bilaterally for above- and below-knee segments. Good impedance waveforms were obtained for the right side with absence of waveforms for the left

below-knee segment (Fig. 16). No temperature gradient was observed between above and below knee on the right side, whereas a 2.25 deg. C. difference between above knee and below knee was determined for the left limb. Because of these findings for the below-knee segment and the patient's age and involvement an above-knee amputation was done.

M.H.   Age 79   Male
Impedance Plethysmography

Above Knee

		Right	Left
Acceleration	ohm/sec	0.289	0.167
Accel Time	M sec	131	172
Deceleration	ohm/sec	0.116	0.079
Decel Time	M sec	229	278
Peak Height	M ohm	19.7	17.8
Pulse Duration	M sec	397	450
Index		0.65	0.619
Area	ohm/sec	5.01	0.619
Pulse Rate	per min	88	88

Below Knee

		Right	Left
Acceleration	ohm/sec	0.238	0.027
Accel Time	M sec	111	87
Deceleration	ohm/sec	0.075	0.026
Decel Time	M sec	254	141
Peak Height	M ohm	12.9	2.2
Pulse Duration	m sec	348	186
Index		0.663	0.5
Area	ohm/sec	2.94	0.31
Pulse Rate	per min	81	81

FIGURE 16.—Impedance Plethysmography for determination of amputation level.

NUMBER OF AMPUTATIONS

In reviewing our surgical service records for the past 15 years, a total of 494 vascular procedures were recorded for a total of 276 patients (Table 1). These procedures were recorded under three categories: 1. lumbar sympathectomy, 2. direct arterial procedure, and 3. amputation. Three hundred and twenty-one sympathectomies, 91 direct arterial procedures, and 82 amputations were completed. Sixty-three of the 276 patients received one or more amputations at some time within the period reviewed.

During 1960-64, 43 vascular procedures were done of which 51 percent were amputations. During 1965-69, 180 vascular procedures were done of which 17 percent were amputations. In 1970-74, 271 vascular procedures were done of which 11 percent were amputation. Thus, there has been a steady increase in the numbers of vascular patients

TABLE 1.—*Number Vascular Procedures Five-Year Intervals (Percent of Total)*

Interval	Lumbar sympathectomy	Direct Arterial procedure	Amputation	Total procedures
1960-1964	16 (37)	5 (12)	22 (51)	43
1965-1969	125 (69)	25 (14)	30 (17)	180
1970-1074	180 (67)	61 (22)	30 (11)	271
Total	321 (65)	91 (18)	82 (17)	494

TABLE 2.—*Above Knee, Below-Knee and Distal Amputations (Percent Total)*

Interval	Amputation			Total
	Above Knee	Below Knee	Distal (Syme, Toe)	
1960-1964	13 (59)	5 (23)	4 (18)	22
1965-1969	13 (43)	12 (40)	5 (17)	30
1970-1974	8 (27)	10 (33)	12 (40)	30
Total	34 (41)	27 (33)	21 (26)	82

coming to the clinic but a decrease in the numbers of amputee patients has occurred.

Of the total amputations done (82), 34 of these were above knee and 48 represent below-knee and distal (Syme, Toe) amputations (Table 2). Thus, distal amputations represent 59 precent of the amputations done during this 15-year period. It should be noted that during the past 5 years above-knee amputations markedly decreased from 59 percent in 1960-64 to 27 percent in 1970-74. Furthermore, there has been a concomitant increase in distal amputations (Syme, Forefoot, and Toe) from 18 percent in 1960-64 to 40 percent in 1970-74.

CONCLUDING COMMENTS

Theoretically an amputation can be prevented. If methods for detecting early signs of vascular problems, as described, are used, the vascular status of the limbs can be evaluated early and appropriate limb salvaging measures instituted to prevent amputation. If utilized during later stages of the disease, an appropriate evaluation can lead to a decision which might salvage the limb. Multiple evaluations are not readily available; however, in a clinic setting, if appropriately utilized, data should be provided sufficient for determining the critical points at which decisions are made.

With respect to decision making, the several case studies presented represent some of the decisions which can and are made following multiple evaluations. We are acutely aware of the increase in the numbers of persons with peripheral vascular disease, many of whom suffer also from diabetes which adds to the complexity of the problem. Precise methods for assessing vascular status and circulatory reserve and the use of objective methods for evaluation of surgical and medical treatment and the efficacy of long-term followup are emphasized.

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SKIN BLOOD FLOW AND HEALING

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INTRODUCTION

The objectives of the Prosthetic Research Program at the VA Hospital San Francisco are:

1. To examine the feasibility and application of immediate postoperative prosthetic fitting to a large group of patients undergoing lower-limb amputation for vascular insufficiency.

2. To establish quantitative criteria to aid in the preoperative determination of an amputation level which contains adequate blood flow for primary healing.

3. To develop additional prosthetic devices to be used for immediate postoperative prostheses at levels distal to below knee, such as transmetatarsal and Syme amputations.

METHODS

Since the commonest amputation for vascular insufficiency at our hospital has been at the below-knee level, a program of below-knee amputation with immediate postoperative prosthetic fitting and ambulation was instituted in the summer of 1967. At that time, it was our impression that there existed no suitable way to determine preoperatively a proper amputation level from the standpoint of circulation. For this reason, it had been our practice to routinely perform amputation at the below-knee level regardless of the status of peripheral pulses, the angiographic distribution of arterial occlusive disease, or skin temperature. The only contraindication to amputation at the below-knee level is the extension of the gangrenous process to the line of incision. Since we had considerable experience with below-knee amputation using conventional operative and rehabilitation techniques, our previous results would serve as guidelines against which we could compare results obtained by using immediate postoperative prosthetic fitting and ambulation according to the Burgess technique.

In order to work out methods for amputation level determination, it seemed most appropriate to direct our investigation toward skin blood

flow determination. Since amputation healing success depends upon skin healing, and since the ability of skin to heal is a function of the blood supply at the level of amputation, then a method which would accurately measure blood flow through the capillary system at a proposed level of amputation ought to provide sufficient data to judge the healing potential at that level. The utilization of the radioactive isotope of Xenon as a means of measuring capillary blood flow in skeletal muscle and skin has been described in the Scandinavian literature. Xenon 133 is an inert, lipophilic substance, whose only means of removal from a depot injection is by passage across capillary cell membrane. The rate of transfer across capillary cell membrane is dependent upon the blood flow through the capillary system since the transport is by a mass-action effect. Thus, if one locally injects Xenon into a tissue and monitors, by the level of radioactivity as a function of time, the rate with which the isotope is removed, blood flow rates can be determined by using a standard clearance formula. This formula states that $F = \frac{\text{Log } 2 \cdot \lambda \cdot 100}{T^{1/2}}$ where F is equal to flow in ml. per 100 gm. tissue per minute, λ is equal to the partition coefficient for Xenon between skin and blood, and T is equal to the Time for a complete decade of radioactivity at the injection site. In order to utilize this method in the skin of lower limbs, our initial evaluation consisted of preoperative measurement of skin blood flow at a point 10 cm. below the tibial tuberosity in the anterior midline over the tibial plateau which corresponds to the anterior skin incision of patients undergoing below-knee amputation. Fifty microcuries of Xenon 133 were removed by a syringe and an intradermal injection was made at that point. A probe capable of measuring radioactive emission was lightly taped to the limb and connected via a rate meter to a strip chart recorder so that the rate of removal of radioactivity at the point of injection could be monitored (Fig. 1). The level of skin blood flow determined preoperatively would then be correlated with healing results in all patients in the amputation series.

RESULTS

In 1972 we carried out a comparative statistical analysis of the two amputation groups. From 1961 to 1966, 55 below-knee amputations were performed on 53 patients using the standard operative technique without immediate postoperative prosthesis. From 1967 through 1971, 53 below-knee amputations were performed on 47 patients with immediate application of a prosthesis combined with postoperative ambulation. Both groups were analyzed for comparability with regard to age, the incidence of diabetes, the level of distal palpable pulse, preoperative ambulatory status, angiographic patterns of disease, and previous vascular reconstructive procedures. An analysis revealed that the two groups were entirely comparable. However, when one compared the results of
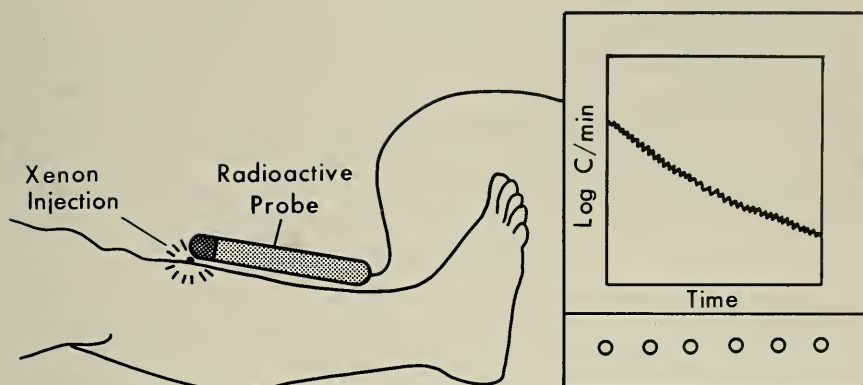
FIGURE 1.—Artist's concept of Xenon skin blood flow measurement showing the probe monitoring radioactivity at the site of injection.

operation there was a striking difference. The healing rate of patients with immediate postoperative prosthesis was 89 percent in comparison to 76 percent using standard amputation techniques. There were no postoperative deaths in the patients with immediate postoperative prostheses. However, the mortality rate was 15 percent in the standard amputation group; the most frequent causes of death in the standard amputation group were pneumonia and myocardial infarction. The results of prosthetic rehabilitation in the two groups also bear comment. All patients who were ambulatory prior to the development of gangrene which necessitated amputation in the immediate postoperative prosthesis group were successfully rehabilitated and became ambulatory on a below-knee prosthesis. In the conventional amputation group, however, 19 percent of the patients who had been ambulatory prior to the need for amputation failed to become ambulatory on a prosthesis. In those patients who did become ambulatory, the time for fitting a permanent prosthesis was only 32 days in the immediate fitting series, in comparison to 125 days in the conventional amputation group. The results of this comparative study demonstrate the clear superiority of immediate postoperative prosthetic fitting not only as a means of accelerating rehabilitation but also as a means of improving the results of postoperative healing.

In reviewing the results of preoperative blood flows and correlation with postoperative healing, the following data were obtained. Thirty-one patients about to undergo 33 below-knee amputations had preoperative skin blood determinations using Xenon 133 clearance. The range in blood flows varied from 2.2 ml. to 15.26 per 100 gm. of tissue per minute. In this group of patients there were three amputa-

tions that failed to heal due to ischemic necrosis. The blood flows in these three amputations, 2.2, 2.24, and 2.36 ml. per 100 gm. of tissue per minute, constituted the three lowest flows in the series. All amputations that had preoperative blood flows in excess of 2.7 ml. per 100 gm. of tissue per minute healed primarily. The high degree of correlation of preoperative skin blood flows using Xenon 133 clearance with ultimate healing success has been most encouraging in this preliminary study.

FUTURE PLANS

Currently armed with information relative to the minimum blood flow required for skin healing, we can begin to apply this information to more conservative levels such as transmetatarsal or Syme amputation. In this manner we hope to be able to offer a more distal amputation level to patients that would otherwise be turned down for a distal amputation based on conventional criteria such as level of distal palpable pulse or angiographic patterns of disease. It is also apparent in our studies that measurement of one point on the circumference of an amputation incision may not adequately reflect the critical area of blood flow; for this reason we are currently studying the use of multiple point flow determinations made possible by employing the Gamma Camera as a radioactive sensing device. Further development in amputation techniques and the use of newer designs of immediate postoperative prostheses for these conservative levels is currently underway.

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WOUND HEALING

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The response of living tissue to trauma—chemical, thermal, or mechanical—is of prime concern to the physician. This is particularly true in surgery. The body, not the surgeon, repairs wounds. The surgeon is responsible for providng optimum environmental circumstances for wound healing consistent with the surgical problems he faces. Gentleness in the handling of tissues is the first surgical axiom. The knife destroys; nature heals. The process of tissue repair encompasses a most complex, interrelated group of biochemical, electrical, and genetic phenomena. Cellular reproduction is the very essence of life.

The amputation is an excellent clinical laboratory for the study of wound healing. Since the surgical trauma is terminal, there are no tissues distal to the operative site which require body support for viability. Physical modalities such as pressure, temperature, and immobilization can be controlled and measured without concern for a more distal uninvolved body segment. The Prosthetics Research Study (PRS) accepted the assignment to investigate immediate postsurgical prosthetic amputee fitting on the basis of a wound-healing study. Ongoing investigations continue to emphasize wound healing as a primary concern.

Our study of the complex and little understood mechanism of wound healing has been confined to the application of certain physical influences on the immediate postsurgical amputation wound. Tissue rest (immobilization) early in the process of wound repair is important. Animals involuntarily splint an injured limb. For centuries this simple fact has been carried over into management of injured body tissue. The degree and duration of immobilization has been the subject of considerable study. The term arthrofibrosis is used to designate the ill effects of prolonged immobilization for joint injuries. The graduated transition from rest to function will depend on the nature of the tissue injury and the type of tissues involved.

The chemical and vascular phenomena involved in injury cause intracellular and extracellular fluid accumulation. Control of this posttraumatic edema has also been incorporated into wound management for hundreds of years. Elevation of the injured part, the application of

compressive dressings, massage, and voluntary muscle activity are all part of conventional limb wound management. Edema control is undoubtedly one of the most important factors for a satisfactory wound-healing environment. Other physical parameters include temperature, humidity, sterility, chemical (gas) composition, intermittent or continuous wound lavage, and the application of chemcial agents.

The PRS immediate postsurgical prosthetic dressing is of rigid design to immobilize and to provide edema control by a pressure interface together with changes of position of the limb, protected weight-bearing under certain circumstances (Fig. 1 and 2), and activity of limb muscles. It also seeks to provide a dry, clean wound atmosphere at average room temperatures. Adequate hemostasis and drainage prevent hematoma
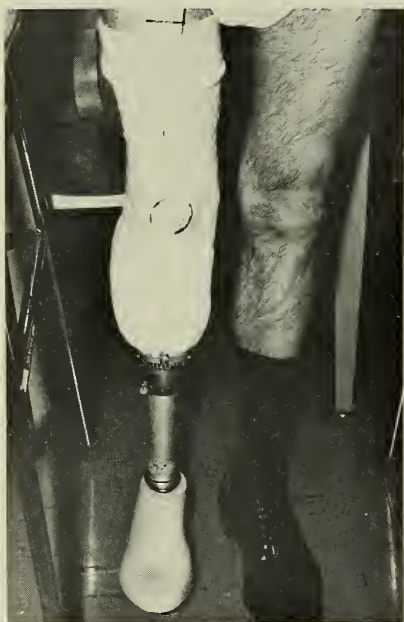
FIGURE 1.—Weight-bearing below-knee immediate postsurgical rigid dressing prosthesis.

FIGURE 2.—Weight-bearing knee-disarticulation and above-knee type of immediate postsurgical prosthesis.

formation. The physical and psychological advantages of patient mobility and ambulation have been highlighted as part of the PRS management protocol. They are considered important but ancillary to the wound-healing process in the stump itself. Over the last several years, observation of the results of this wound management (Fig. 3 and 4) through many hundreds of cases has allowed us to upgrade and simplify techniques. Each amputation we have done using the PRS system has been viewed as a wound-healing experiment. Documentation includes

the clinical records, routine serial photographs, measurements, and in certain cases, pressure, temperature, and skin tension readings in certain areas of the healing stump. Based on these data, we have modified and improved our system. The below-knee postsurgical dressing is illustrated in its various components (Fig. 1). Immediate postsurgical dressng at a level other than the lower limb is also shown (Fig. 5).
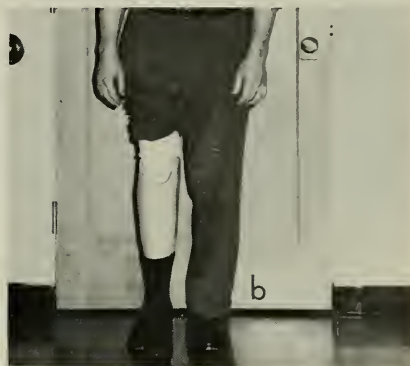
FIGURE 3.—Demonstrates early wound healing as a result of using reconstructive-plastic surgical approach and rigid dressing and postsurgical prosthetic management.

FIGURE 4.—Below-knee amputation showing primary wound healing with PRS management.
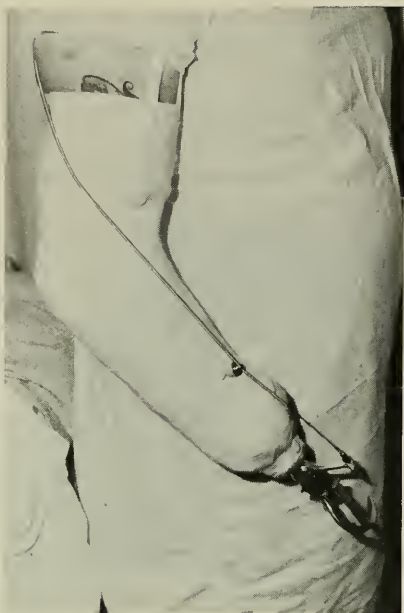
FIGURE 5.—Below-elbow immediate post-surgical prosthesis.

In March 1974 we entered an agreement with members of the Biomechanical Research and Development Unit, Department of Health and Social Security, Roehampton, London, in the investigation of a controlled environment chamber for the treatment of postoperative wounds of the upper and lower limbs, including amputation stumps (Fig. 6). Preliminary information from this coordinated investigation will be jointly submitted. We are enthusiastic about the data and results obtained with the Roehampton wound environment system.

This brief discussion on wound healing relates only to those factors under investigation at the Prosthetics Research Study. The complex nature of the process at the cellular level is recognized. Information obtained from all sources must continue to be incorporated into clinical studies of the type we now pursue.

FIGURE 6.—Controlled environment chamber applied immediately after below-knee amputation. Environment sterility and gas composition are controlled in this (Roehampton) unit.

DEVELOPMENT OF REFINED FITTING PROCEDURES FOR LOWER-LIMB PROSTHESES

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Miami, Florida 33152

Our contract title is "Development of Refined Fitting Procedures for Lower-Limb Prostheses" because our past work has centered around lower-limb prosthetic suspension systems. The patellar tendon supracondylar (Fig. 1) system with soft medial wedge was developed at the University of Miami Medical School and is now our standard means of treatment for below-knee amputees. Also, the expandable Syme prosthesis (Fig. 2) providing suspension without windows was developed by the University of Miami Medical School and has become the routine device for Syme's amputees here. Many years of research have gone into the Taslon suspension for above-knee and below-knee amputees (Fig. 3), but this project has been temporarily set back until a better material can be found. In the meantime a system utilizing thermoplastic removable sockets is being developed. With this system, a socket is hand-formed from polypropylene with the aid of vacuum (Fig. 4), and a rigid, polyurethane outer structure is fabricated around it (Fig. 5). The final prosthesis is then laminated over the formed foam structure (Fig. 6). The socket is then removable, for ease of modification as the stump dimensions change (Fig. 7). The socket may be reheated locally for minor adjustments or a new socket fabricated for major adjustments. Then the new or modified socket is placed back in the old prosthesis with a small additional amount of urethane foam to refit the socket to the system. Above-knee, below-knee, and below-elbow patients have been successfully fitted with this system to date.
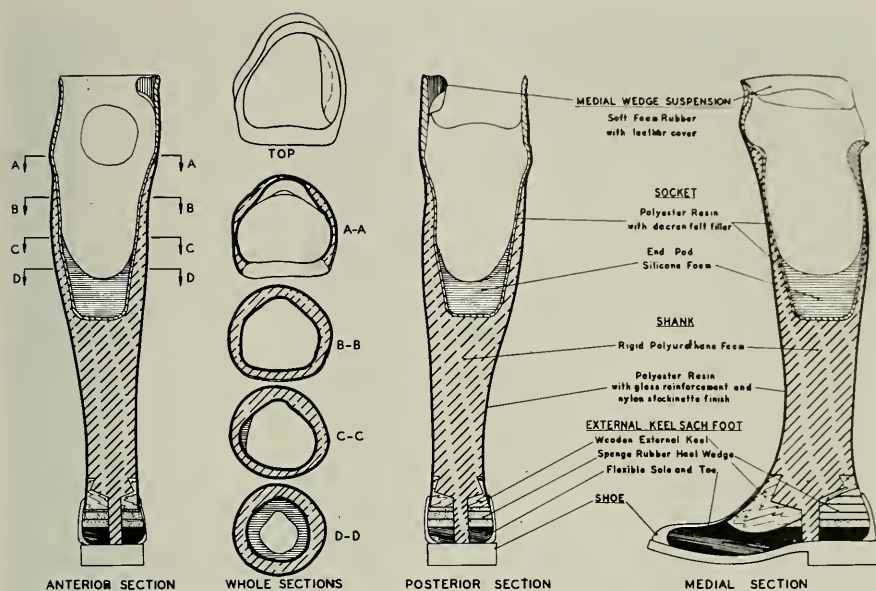
FIGURE 1.—Patellar tendon supracondylar system.

FIGURE 2.—Expandable Syme prosthesis.

FIGURE 3.—Taslon socket system.

FIGURE 4.—Forming polypropylene socket below knee.

FIGURE 5.—Polypropylene socket in rough polyurethane foam shell, below knee.

FIGURE 6.—Final prosthesis with laminated shell, below knee.
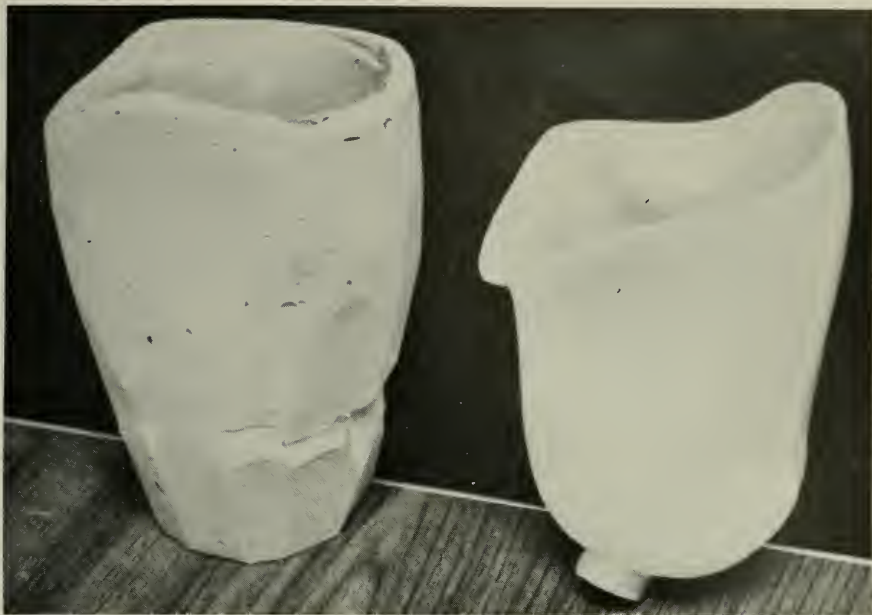
FIGURE 7.—Polypropylene socket removable from polyurethane shell, above knee.

All during this time, developments have been progressing in fracture orthoses. In the past 2 years this clinically applied research has accelerated, and the use of thermoplastics has provided lighter, more functional and more versatile orthotic designs (Fig. 8). Intra-articular fractures of the tibial plateaus are now being braced with modifications to the tibial fracture orthosis (Fig. 9). Either a medial knee joint, and/or a lateral knee joint may be added with a thigh extension to the existing orthosis to suit the particular geometry of the plateau fracture. Fractures of the femur which normally could not be treated by bracing, may now be treated with an orthosis which has an added pelvic sling. Forearm fractures are treated in an orthosis which allows elbow and wrist motion but no supination or pronation (Fig. 10). Colles fractures are also being treated with an orthosis which provides use of the limb. The wrist and elbow are free in flexion but limited in extension, and the forearm is held in supination (Fig. 11). Special additions for difficult cases include an elbow joint extension (Fig. 12). Humeral fractures are also being braced now on an experimental basis allowing wrist, elbow, and shoulder motion (Fig. 13).

FIGURE 8.—Polypropylene insert development for tibial fracture brace.

FIGURE 9.—Tibial fracture brace with knee joints and thigh extension.
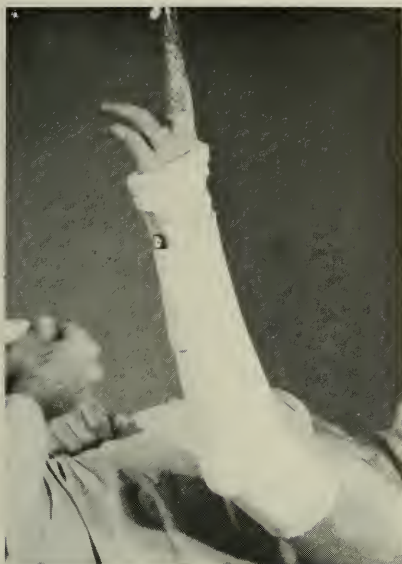
FIGURE 10.—Forearm fracture brace holds forearm in neutral position, allows full volar and dorsal flexion of wrist, and allows flexion but not full extension of elbow.
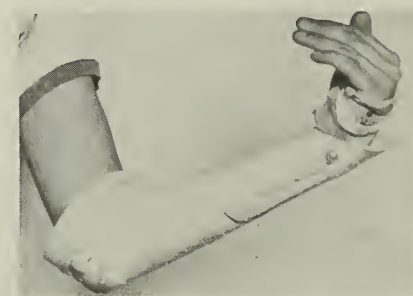
FIGURE 11.—Colles fracture brace holds forearm in supination, allows volar but not dorsiflexion of wrist, and allows flexion but not full extension of elbow.
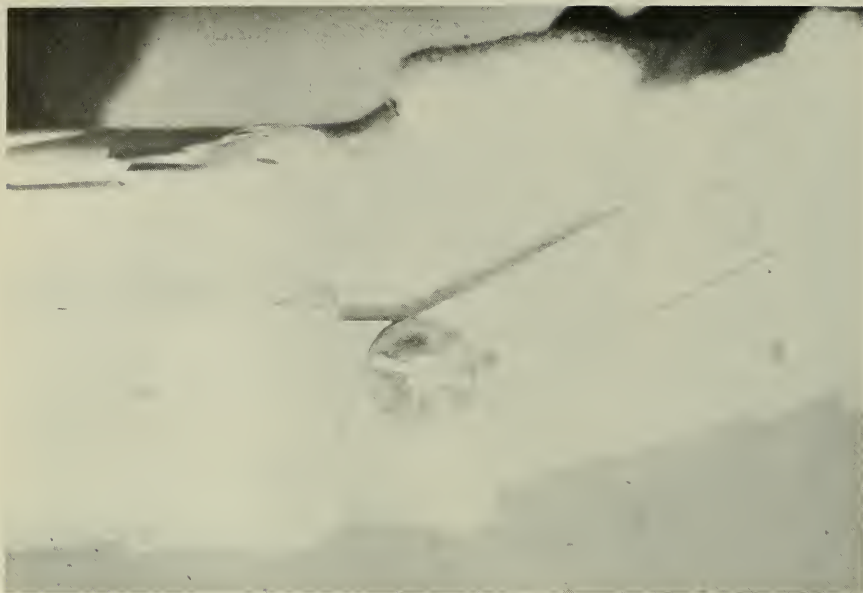
FIGURE 12.—Elbow joint extension for Colles fracture brace to aid in limitation of pronation-supination.

FIGURE 13.—Humeral fracture brace allows flexion and extension of elbow and shoulder.

Also, in orthotics design a series of polypropylene AFO's have been developed in four standard sizes to be used as an "off the shelf" item for patients with minimal ankle involvement (Fig. 14). It has been our experience that about 80 percent of the hemiplegic patients requiring thermoplastic AFO's can be adequately fitted with this standard, non-custom design. Recently, standard modifications have been developed as "add-on" devices to the standard AFO for patients with minimal knee involvement or those which require more ankle support (Fig. 15).

FIGURE 14.—Polypropylene AFO's in standard sizes.

FIGURE 15.—Polypropylene AFO's with extensions.

With this background in orthotics as well as prosthetics it has been decided that all types of orthotic, lower-limb cases should be included as possible candidates for development work along with prosthetic cases. Therefore, our present research centers on difficult and unusual problem cases in lower-limb orthotics and prosthetics. Individual nonroutine cases, rather than general classes of problems or devices, are treated and documented for research. Prospective cases are evaluated for the program by a team consisting of physician, orthotist-prosthetist, and engineer. Initial evaluation consists of:

1. Decision to include or exclude from research program.

2. Physical examination by standard forms if prosthetic patient. Physical examination by technical analysis form if orthotic patient.

3. Prescription for new type of device.

4. Photos of patient with and without old device, and gait analysis with and without old device.

5. Initiation of file for the patient containing records of the above plus a list with brief comments on each visit the patient makes, a cover sheet with vital patient information and brief history, and a form for each major visit which records: a. evaluation of treatment by clinical team and by patient; b. gait analysis calculations of rate of ambulation, stride length, and stride rate; and c. description of device used at that visit. The patient file is updated with each visit. Once an experimental device is deemed adequate by the patient and the clinical team without further major modification, the patient is scheduled for a series of routine followup visits to commence within 2 weeks and repeat once per

month for a minimum of 1 year. Each scheduled visit includes a gait analysis (Fig. 16) and evaluation of progress by clinical team and patient.
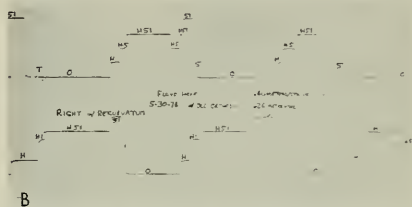
FIGURE 16.—a. Gait analysis includes load distribution and foot position analysis by barograph and rate and sequencing analysis using Dr. Perry's foot switch system. b. Recording time of heel (H), first metatarsal (1), fifth metatarsal (5), and toe (T) contact with the floor.

Presently, two prosthetic patients and seven orthotic patients have been included in the case study program. An example orthotic case is shown in Figures 17 through 30.

FIGURE 17.—Patient with original orthosis.

FIGURE 18.—Patient without orthosis.

FIGURE 19.—First experimental orthosis-posterior upright with polypropylene hinge.

FIGURE 20.—Second experimental orthosis with polycarbonate compression members for extension stop.
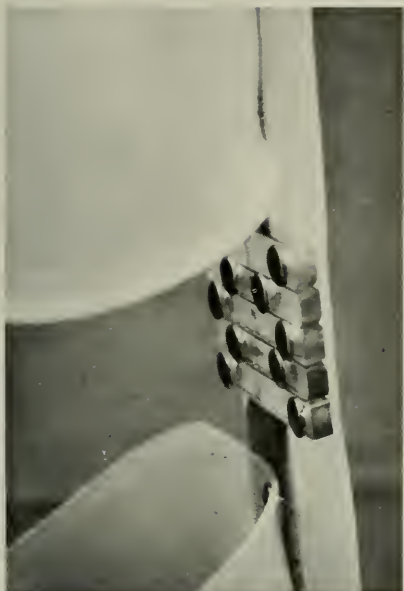
FIGURE 21.—Closeup of second experimental knee mechanism.

FIGURE 23.—Fourth orthosis using modified ankle joints and polypropylene shells.
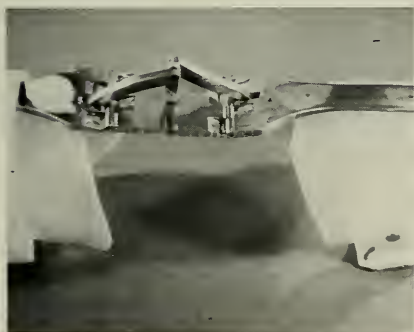
FIGURE 22.—Third orthosis with aluminum linkage.

NAME: ~~Carter~~ ~~Anderson~~   HOSPITAL #_____

ADDRESS: 10100 SW 42 ST   PHONE # 226·5·39A

SEX: M   AGE: 22   INITIAL DATE: 4-10-74

REASON FOR INCLUSION IN PROGRAM:_____

_____

SUMMARY OF DIAGNOSIS

PRIMARY:_____

_____

SECONDARY:_____

_____

INITIAL SOLUTION: LOCK RIGHT KNEE (OFFSET KNEE JTS) FREE LEFT KNEE
PP SHELLS, DOUBLE UPRIGHT ALUMINUM, ANKLE JTS. SAME AS BEFORE

SECONDARY SOLUTION:_____

_____

RESULTS AND CONCLUSIONS:_____

_____

_____

_____

FIGURE 24.—Patient information form.
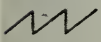
TECHNICAL ANALYSIS FORM · **LOWER LIMB** Revised July 1972

Name _____ No._____ Age _____ Sex _M_

Date of Onset _age 3 mo_ Cause _____

Occupation _____ Present Lower-Limb Equipment _____

Diagnosis _____ _____

Date _____ (signature)

Ambulatory ☐ Non-Ambulatory ☐

MAJOR IMPAIRMENTS:

A. **Skeletal**
   1. Bone and Joints: Normal ☐ Abnormal _____
   2. Ligaments: Normal ☑ Abnormal ☐ Knee: AC ☐ PC ☐ MC ☐ LC ☐
      Ankle: MC ☐ LC ☐

   3. Extremity Shortening: None ☑ Left ☐ Right ☐
      Amount of Discrepancy: A.S.S.-Heel_____ A.S.S.-MTP_____ MTP-Heel_____

B. Sensation: Normal ☑ Abnormal ☐
   1. Anaesthesia Hypaesthesia ☐ Location:_____
      Protective Sensation: Retained ☑ Lost ☐
   2. Pain ☐ Location:_____

C. Skin: Normal ☑ Abnormal:_____

D. Vascular: Normal ☑ Abnormal ☐ Right ☐ Left ☐

E. Balance: Normal ☑ Impaired ☐ Support:_____

F. Gait Deviations:_____

G. Other Impairments:_____

———————————————— LEGEND ————————————————

⊕ ↑→ = Direction of Translatory Motion

⊕ 60° = Abnormal Degree of Rotary Motion

⊕ 30° 1 CM. = Fixed Position

⋀⋁ = Fracture

Volitional Force (V)
V = Normal
G = Good
F = Fair
P = Poor
T = Trace
Z = Zero

Hypertonic Muscle (H)
M = Mild
Mo = Moderate
S = Severe

Proprioception (P)
V = Normal
I = Impaired
A = Absent

D = Local Distension or Enlargement

= Pseudarthrosis

= Absence of Segment

FIGURE 25.—Technical analysis form, page 1.

127
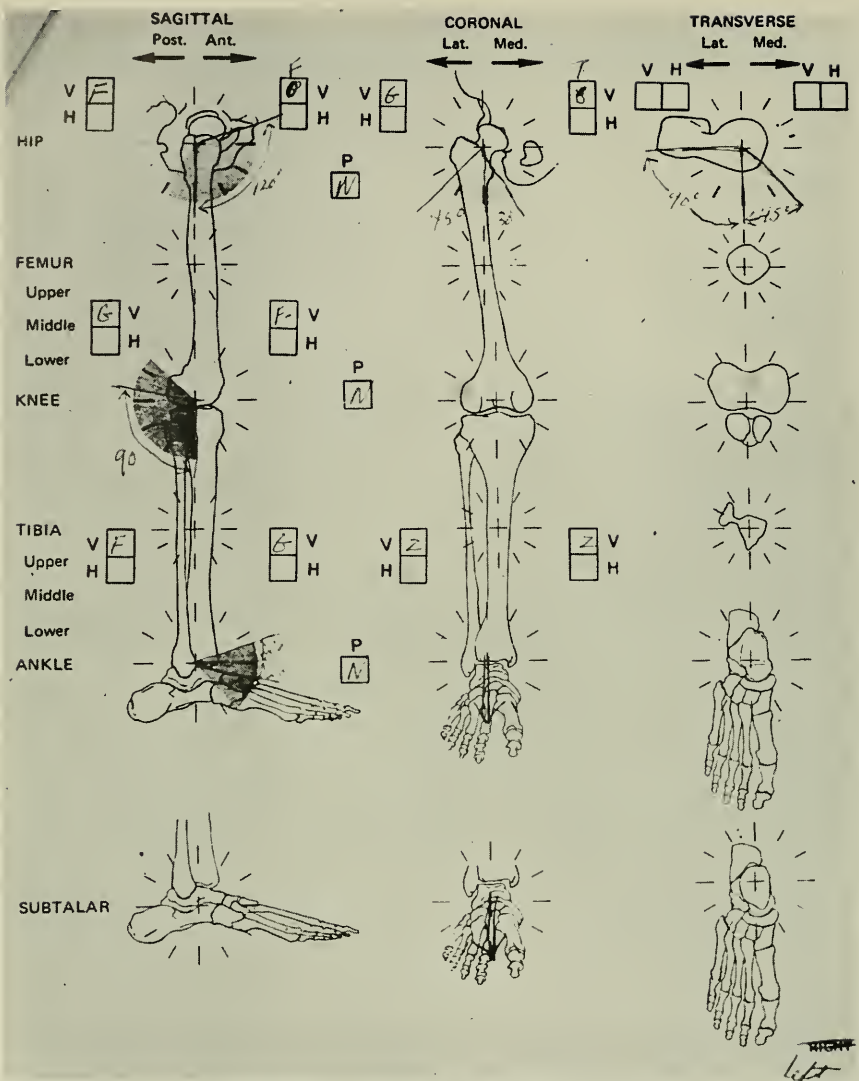
FIGURE 26.—Technical analysis form, page 2.
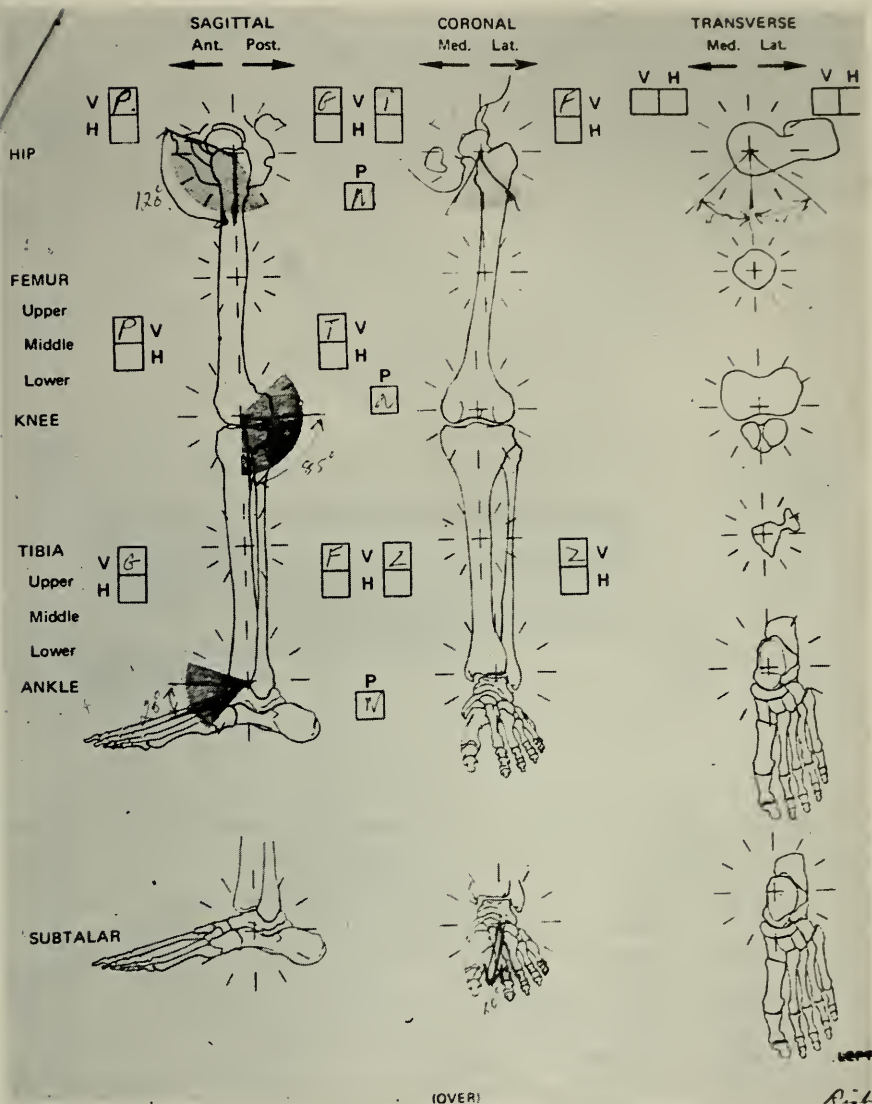
FIGURE 27.—Technical analysis form, page 3.

Summary of Functional Disability _____

_____ *Difficulty donning @ AKO* _____

_____ *(handwritten text)* _____

_____ *for (handwritten text)* _____

Treatment Objectives:

Prevent/Correct Deformity ☐   Improve Ambulation ☑

Reduce Axial Load ☐   Fracture Treatment ☐

Protect Joint ☑   Other *facilitate ease of donning*

ORTHOTIC RECOMMENDATION

LOWER LIMB		FLEX		EXT		ABD		ADD		ROTATION Int.		Ext.		AXIAL LOAD
HKAO	Hip	F	r	F	F	F	F	F	F	F	r	r	F	
KAO	Thigh													
	Knee	H	F	H	F	H	H	H	H					
AFO	Leg													
	Ankle	F (Dorsi) 3 9° 5 9° (Plantar) F												
	Subtalar									(Inver.) H		(Ever.) H		
FO Foot	Midtarsal	F	F	F	F									
	Met.-phal.	l	r	F	F	r	F	r	F					

REMARKS: *(handwritten text)* Mostly, front AKO on @ below specification, then facilitate angle of rgt AKO if possible to walk in few weeks @ slow front @ AKO as

FIGURE 28.—Technical analysis form, page 4.

APRIL 12. Attempted posterior upright orthosis again with flexible PP strap & PC block compression stops in extension & PP molded shells. Added SS cable tension member for added strength but cable fitness pulled out. Try 4 bar linkage next.

MAY ? Posterior 4-bar doesn't stop adequately made in Alum. Need support links to stop in extension. Also needs new high anterior wall on thigh section to control hip extension

MAY 30 Posterior 7-bar linkage stops in extension adequately but hip flexion moment pushes on high anterior wall of thigh shell when being seated, thus causing knee to flex inappropriately. Need forced flexion in knee linkage. Modified present orthoses for temporary use.

JUNE 19 New shells with double upright childs toe lift ankle extensions for knee joints gives adjustable control of knee extension stop. But thigh section too low anteriorly and impinges on distal, medial portion of thigh Foot & calf section too flexable at ankle needs ribbing + less trimming in posterior section. Pt. suggested single axis ankle joint in the PP parts instead of posterior leaf. Old orthosis beyond repair

JUNE 27

FIGURE 29.—Record of each individual visit.

EVALUATION OF DEVICE

DATE: 4-19-74   VISIT: 1   POST FITTING: -2 WKS

A. <u>EVALUATION BY PATIENT</u>

   COMFORT:_____

   COSMESIS:_____

   FUNCTION:_____

B. <u>EVALUATION OF CLINICAL TEAM</u>

   COSMESIS:_____

   FUNCTION:_____

C. <u>GAIT ANALYSIS</u>

   RATE OF AMBULATION:_____

   STRIDE LENGTH:_____

   STRIDE RATE:_____

D. DESCRIPTION OF DEVICE ☒ ORIGINAL DEVICE ☐ EXPERIMENTAL DEVICE

FIGURE 30.—Major followup visits form.

TRANSFERRING LOAD TO FLESH

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New York University
26-36 Stuyvesant Street, New York, New York 10003

ABSTRACT

Prosthetics soft tissue trauma is attacked with a combination of theoretical and experimental tools. A novel socket design results, accentuating flesh stress relief at the socket brim. Currently, the novel socket has been fitted to two subjects with long histories of stump trauma; field test results are not yet available.

THE PROBLEM

My problem is the prevention of soft tissue trauma resultant from prosthetic devices. Specifically, how is a prosthesis to be joined to the body so as to prevent lesions, cysts, plugs, abrasions, etc. We cannot examine all these problems in one session, so let us consider one problem only in some detail.

Consider the cyst problem. The curious thing about cysts is that they usually form *outside* the socket, where one would think the mechanical loading would be low (Fig. 1). To quote the dermatologists Allende et al. (1), "Cysts do not occur where the rim of the socket touches the skin . . . instead, the cysts are often found 1 to 2½ cm. above the rim." To quote James Foort (2), "Often when the stump is refitted and the cysts contained within the socket, they will clear up." It would appear that *some* stress is greater outside the socket than inside. But what stress is involved, and what can we do about it?

FIGURE 1

To explore the problem, we need a description of stresses that result when something soft—flesh—is pressed by something hard—the socket. In particular, we are interested in what happens to the flesh just beyond the socket. Our theory was taken whole from the Russian mathematicians Vlasov and Leontev (3). The problem becomes one of applying the theory, of developing equations describing our special cases. The development is a tedious business and will not be given here. In summary, we are combining the classic theory of elasticity with newer variational approaches, plus a realistic model of flesh as a material. The entire derivation has been given in various issues of BPR going back to 1971, for those interested in the details (4,5).

RESULTS AND DISCUSSION

Some of the results are given in Figure 2, which shows the distribution of compressive stress in flesh produced by pressing a dull-pointed object, say a pencil, into the flesh surface. Obviously, the stress under the pencil will be large. Note, however, that as we move away in a lateral sense from the pencil, the stress falls quickly. What this implies is that no matter how great a compressive stress is applied to the brim area, the transfer of stress to remote areas outside the brim is unlikely to produce large values. Even more discouraging are the results of Figure 3, in which a rigid block representing the socket is pressed into 1 in. thickness of flesh supported by bone. Note that the compressive stress falls off immediately outside the loading block and dissipates within less than 1 in.

We are looking for some form of stress that is *greater* outside the loading block than within the confines of the block. The results of Figures 2 and 3 suggest that compressive stress is unlikely to be the culprit.

There are but two forms of stress—normal and shear. Normal (compression and tension) does not fit the facts; therefore, let us look at shear. The same analytical procedures applied to shear stress produce the following result: shear stress is roughly equal to the rate of change of compressive stress with distance. In other words, where the compressive stress is relatively "flat" (see Fig. 3), there is no shear stress. On the otherhand, where the compressive stress changes rapidly, as it does *beyond* the edge of the loading members in Figure 3—the shear stress is a maximum. Or, in the case of a socket, the shear stress will peak *outside* the brim.

Consider shear stress as the culprit. It peaks outside the socket, fitting the observation of Allende et al. Shear stress disappears inside the socket, fitting the Foort observation that cysts frequently clear up if the

POISSON'S RATIO = 0.23   POISSON'S RATIO = 0.33   POISSON'S RATIO = 0.41
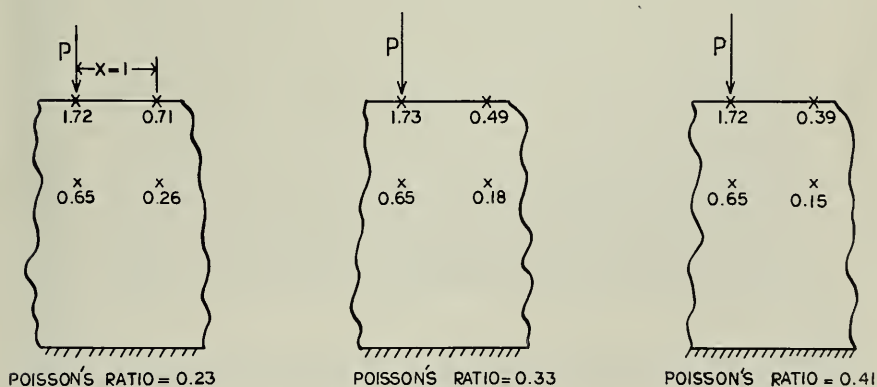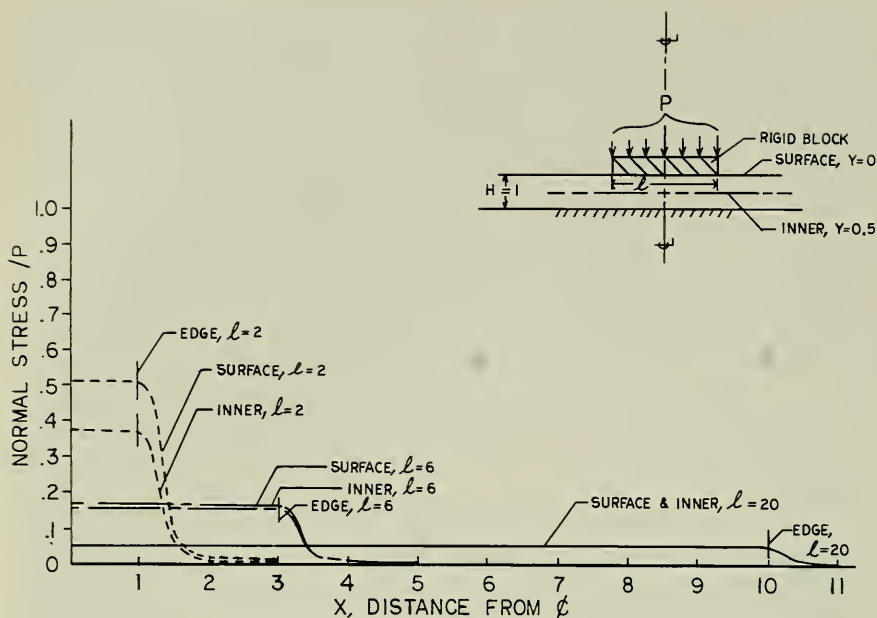
FIGURE 2

FIGURE 3

affected area is moved within the socket. While no causal relationship between cysts and shear stress has been developed, the association between the two seems interesting enough to pursue.

The next step is to design a socket with the least possible shear stress. A number of false starts were made here. Figure 4 shows the shear stress associated with a diaphragm-like member similar to a garter. Note the severe shear stress developed at the ends; the concept is poor. A better design is shown in Figure 5. Unfortunately, it would appear difficult to fabricate. Still, it demonstrates what is desired—a gradual transition from full socket thickness to a thin brim. The long transition—and the longer the better—insures low shear stresses. At this point, we felt that theory had been pushed as far as profitable, and we switched to experimental work, looking primarily for confirmation of the analytical work.

The ideal experimental procedure is one involving direct testing on human subjects. Unfortunately, this would involve instrumentation implants and biopsies. These are not easy to arrange. As a substitute, we have employed a material called Spence-gel in the role of a model flesh (Fig. 6).
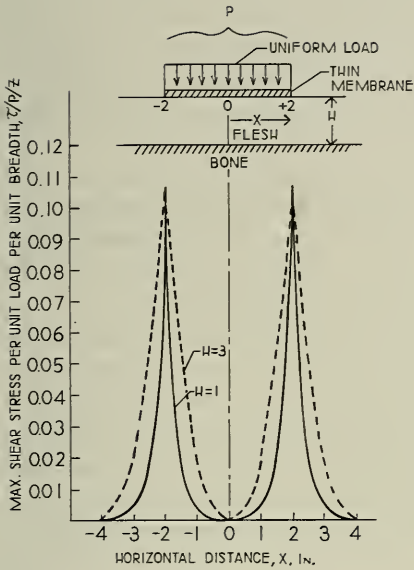
FIGURE 4
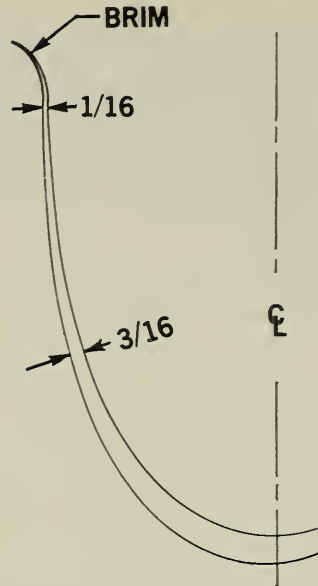
LOW SHEAR DESIGN 1

FIGURE 5
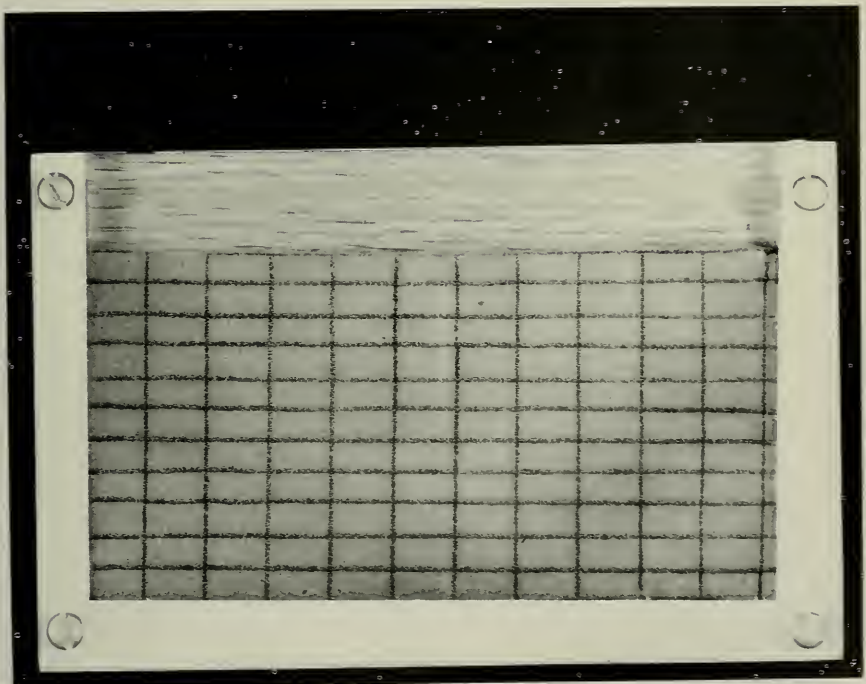
FIGURE 6

The basic idea is to press upon the edge of a slab of Spence-gel trapped between rigid flat plates. One of the plates is a window, through which we can see the deflections of the gel. Before testing, the slab is marked with a coordinate system. Compressive stress is shown by a shortening of any of the rectangles when under load. Shear stress is directly proportional to the departure from a right angle of the gridlines at any intersection of interest.

A typical test is shown in Figure 7. Here a dull chisel is pressed into the simulated flesh under a load of 1.1 lb. The reason for picking this type of loading—the dull chisel—is that the theoretical solution is particularly simple. Therefore, even though the dull chisel load is impractical, it lends itself to a good check of theory versus experiment.

A comparison of the predicted and experimentally determined compressive values for the dull chisel case are given in Figure 8. The curves represent the theoretical prediction of compressive stress along certain contour lines and the points are the experimental results. The quantitative agreement is disappointing; discrepancies as large as a factor of two appear between theory and experiment. It is not clear to me as to where the errors originate—both the theory and the experimental work con-
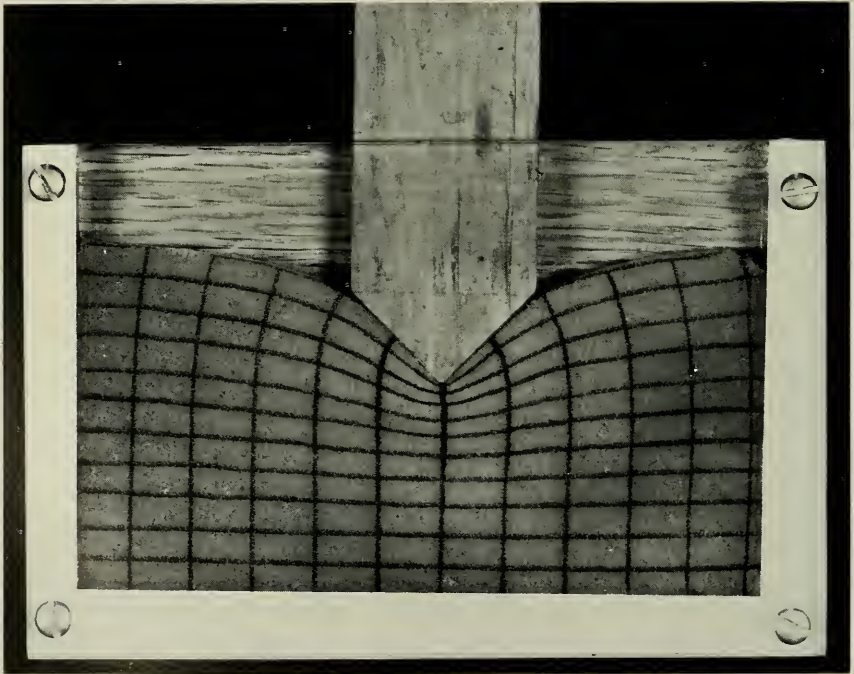
FIGURE 7

tain severe oversimplifications. Certain of these assumptions are in direct conflict. For example, we assume that any vertical gridline remains vertical in our theoretical work, whereas we make no such assumption in our experimental work.

Granted that the lack of *quantitative* agreement is disappointing, it should be noted that there is total agreement in a qualitative sense. That is, every significant trend is supported by both theoretical and experimental results. Remembering that our goal is the reduction of trauma, our ability to predict and understand stress trends would appear an adequate tool. Either the analytical or experimental treatment is sufficient for this purpose.

How do we reduce shear stress? The basic idea is to reduce the rate of change of compressive stress. Consider Figure 9. Here we have the dull chisel case again, except we have inserted a thin cover plate between the chisel and the flesh. Comparing Figures 7 and 9, you will note that the cover plate reduces the magnitude of the shear stress under the chisel to zero and creates relatively small shear stress values at the outer edges of the cover plate. In short, it is possible to influence both the magnitude and location of shear stress by control of the means of load application.
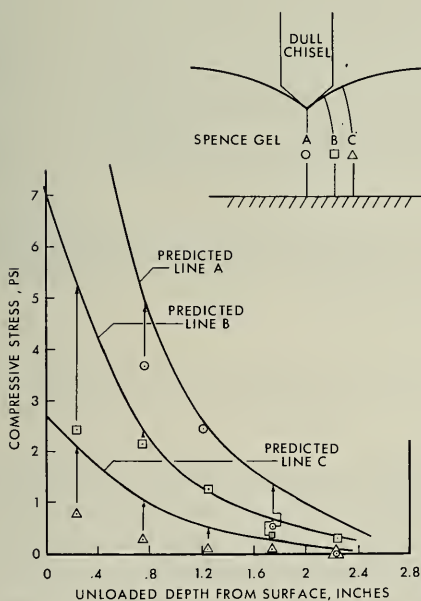
FIGURE 8
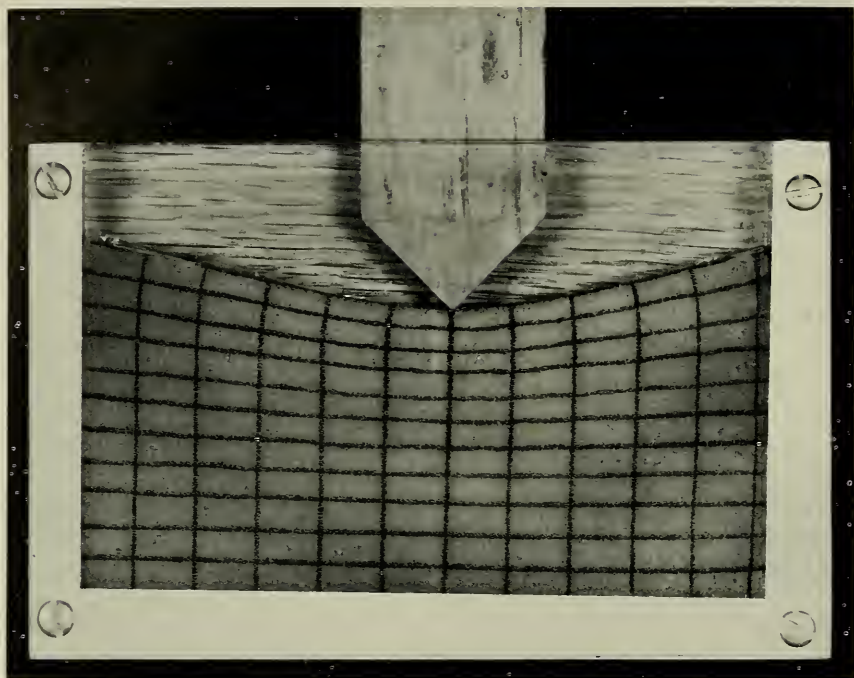
FIGURE 9

A simulated socket brim sustaining an inertial load owing to stump acceleration is shown in Figure 10. Note that significant shear stress exists only at the brim or outboard of the brim. Once into the socket, shear stress disappears.

What is wanted in a socket brim is something like the cover plate effect of Figure 9, some way of reducing the compressive stress gradient at the brim.

At this point, I worked with a prosthetist to put together a practical design (see Fig. 11). The socket consists of an inner layer compounded of flexible resin and an outer layer compounded of a rigid laminate. The outer layer is removed wherever we desire a low shear stress, i.e., in the vicinity of the brim. In this manner, deflection of the inner layer serves
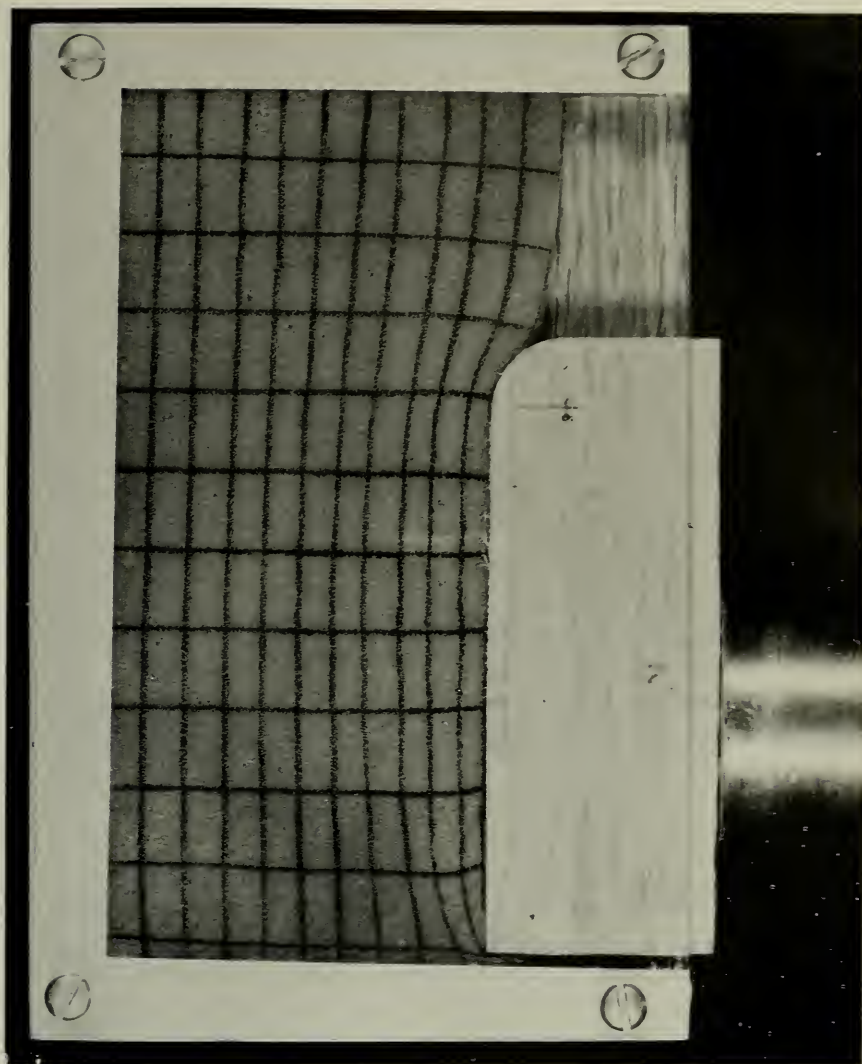
FIGURE 10

to reduce the compressive stress gradient at the brim. The approach is analogous to that of the cover plate of Figure 9, and the brim solution of Figure 5, yet avoids the awkwardly thin sections of these approaches. Wherever considerable load must be taken at the brim, as at the ischial seat, the outer layer is simply left intact.

LOW SHEAR DESIGN 2
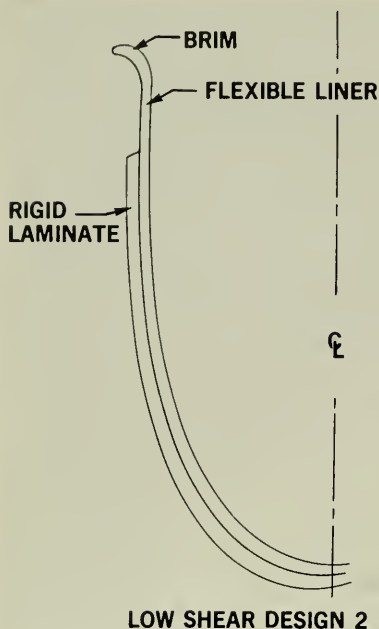
FIGURE 11

Two subjects have been fitted with such sockets. Both are hard cases with long records of stump trauma in the brim vicinity. Medical inspection is being conducted by Dr. Emilio Ejercito of the Castle Point Veterans Administration Hospital Staff, on a before, during, and after basis with frequent followup examinations. To comment on the results of two fittings is clearly premature; we shall await more fittings and the passage of some time before field test results are announced.

We plan to fit a total of six hard cases within the next year. Hopefully, this should be sufficient to indicate the presence or absence of merit in our approach.

CONCLUSION

We have dealt with brim area trauma in this paper and in the cyst problem in particular. This problem area is a fair example of our task and approach. It would be our hope to extend this type of approach to prosthetic flesh trauma problems in general.

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DEVELOPING A PERMANENTLY ATTACHED ARTIFICIAL LIMB

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INTRODUCTION

There is nothing new concerning the broad concept of having a permanently attached artificial limb. Our endeavor has been to determine if such a dream is feasible. We think it is.

Problems as complex as developing such a device must be approached by dividing them into small, well-defined problem areas and grouping these into sound research projects. The group of problems that must be given first priority are those pertaining to tissue interfacing.

This type of artificial limb would be designed around a direct skeletal extension protruding through the skin. A removable articulating joint would be affixed to the protruding portion. An external portion might also have the potential of being controlled by the primary skeletal muscles by way of artificial tendons exiting through skin tunnels.

To achieve the above, it is necessary to find solutions to the following four major problem areas:

1. Finding a material for skin interfacing that would create an absolute bacterial barrier, be tenacious in its attachment, and have the strength and durability for long-term function.

2. Developing a material and/or technique to interface with bone which would give long-term stability and whose mechanical impedance would closely match that of bone.

3. Developing techniques whereby artificial tendons could be strongly anchored to the musculotendinous portion of large skeletal muscles, then brought through the skin, and finally coupled to an external articulating prosthetic device.

4. Designing an external device which would be controllable by the artificial tendons and would incorporate sufficient shock absorbing techniques to protect the bone interface from trauma.

Before describing these problems in detail, it might be well to briefly outline the advantages that such a device would have over existing prosthetic devices:

1. Because the skeletal extension provides the weight-bearing element rather than interfacing with a cup and soft tissue, the total prosthetic device would be more stable.

2. This increase in stability should allow the wearer to perceive a more realistic and appropriate kinesthesia.

3. Since no forces are transmitted through soft tissue, there should be fewer soft tissue problems upon weight-bearing.

4. An important theoretical advantage would be the potential of bringing the amputated portion of the limb back under the control of existing skeletal muscles. There would be a tremendous advantage to the wearer in being able to flex and extend a simple joint. No longer would an above-knee amputee have to rely on gravity and total body attitude to produce a positive swing through.

SKIN INTERFACING

Many approaches have been used in an attempt to bring tubes, lead wires, conduits, and rods through the skin so as to prevent these exiting holes from becoming infected. Usually a sinus tract is formed which ultimately leads to either a cellulitis or an abscess.

Epithelial cells seem to have an inborn desire to be bound on their periphery by other epithelial cells. When a break in the integument occurs some cells are left with a side unsupported by other epithelial cells. As the repair process occurs, epithelium continues to grow until it reaches raw sides of other epithelium. If an obstruction is placed in its path, such as a tube or rod, the epithelium, unable to grow through or over the tube, proceeds deep into the tunnel until the deeper organs are encountered or until the object has become marsupialized. Such is the case of the carbon buttons shown in Figure 1. These buttons have been implanted for 7 months, during which time the wearer experienced little difficulty. However, upon removing these buttons it became apparent that they were no longer implanted but were residing in a completely marsupialized pouch. Biopsies taken from similar experiments corroborate these findings as clearly demonstrated by the photomicrograph shown in Figure 2.

During the 7-month implantation of the carbon buttons shown in Figure 1, electrical impedance measurements were taken. Little change in impedance could be demonstrated during this 7-month interval. For skin electrodes requiring long-term usage, carbon buttons appear ideal. However, for skin interfacing of the type required for deep penetration, carbon has little or no application.

The problem of skin interfacing was first brought to our attention to meet the needs of transmitting power through the chest wall in order to drive an artificial heart. Success in solving this problem using various

FIGURE 1.—Biocarbon buttons removed after 7 months' implantation. Notice absence of bleeding. Marsupialized pouch was found to be completely lined by squamous epithelium. Buttons were obtained through the courtesy of Mr. Jim Benson, Tarzana, California.
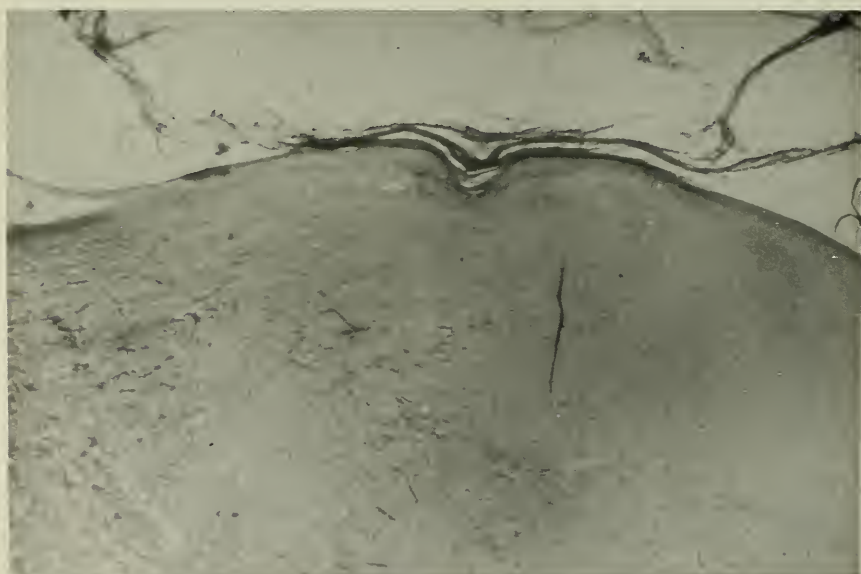
FIGURE 2.—Biopsy taken through the bottom center of a marsupialized pouch. In this case, the carbon button had been implanted for 12 months in the dorsum of a goat. Buttons were obtained through the courtesy of Dr. Jack Bokros, Gulf Atomic Research.

types of velour fabric led us into tangential problem areas, such as the development of a permanently attached artificial limb.

Many types of velour (Fig. 3) have been tried in an effort to find the one most suitable. A recent contract with the National Institute of Arthritis and Metabolic Diseases provided us the opportunity to test velours, foamed plastic, solid core rods, carbon buttons, and nonwoven fabric in a search for a suitable skin interface for the arteriovenous shunt used in hemodialysis.

FIGURE 3.—Enlarged closeup of the velour-type weave. Notice the wicket-like construction of the monofilament weave which presents large interstices through which tissue can grow.

A summary of these findings are listed, and the materials bonded to the test rod and the results of these tests are shown in Table 1.

TABLE 1.—*Materials Bonded to Test Rod and Results*

Material	Results
1. Nylon or Dacron velour	Excellent, only problem is eventual extrusion of rod—"Growth Phenomenon."
2. Polypeptide with rough cast surface or nonwoven fabric	Good for short-term usage but is biodegradable.
3. Polyurethane foam	Good for short-term usage but not as predictable as nylon velour.
4. Nylon foam	Poor—probably due to closed cell construction of foamed material.
5. Vitreous carbon buttons	No wound infections seen but excisional biopsies demonstrated complete marsupialization of implant.
6. Solid uncoated Silastic rod (used as control)	Sinus tract invariably formed—easily withdrawn if retaining suture was removed.

It is obvious from Table 1 that of the materials tested to date, the only ones to give satisfactory results are the velour fabrics. This is not meant to imply that there is no need to continue our search for better materials.

Our methodology in obtaining the above tabulated data was to bond the test material to a solid core Silastic® rod that could then be implanted into the test animal. In order to more easily observe the test implant, the dorsum of the animal was selected. Goats, dogs, and pigs have been used as test animals. Of these, goats are easiest to care for and, since they ignore the implant site, more reliable data can be obtained. Figure 4 shows a test implant being biopsied after having been in place for several months.

One of the problems encountered using velour on the surface of these test implants was the tendency for the implant to "grow" —or rather, to be slowly extruded after a prolonged period of time. This "growth phenomenon" had a steady, predictable growth rate of approximately 1 mm. per month. Various theories were proposed to explain the extrusion of these implants. All but one have since been discarded.

Further experimentation and observation have convinced us that there are two factors involved. First is the fact that certain polymers are accepted by epithelial cells as "being" epithelial cells. The desire to have its bare side joining other epithelial cells is therefore satisfied. This must mean there has been a chemical wedding and not a simple mechanical entanglement of the tissues throughout the interstices of the fabric. Since the epithelium stops its search, no sinus tract is formed. Microscopic examination through an implant area (Fig. 5) demonstrated the relationship of each monofilament strand to adjacent cells. Secondly, there is microscopic evidence showing individual strands of velour en-

FIGURE 4.—Test implant demonstrating method of excisional biopsy. Note variations in shading of velour brought about by the "growth phenomenon."

trapped in the cornified layer of epithelium. Since the cornified layer represents nonviable, relatively inelastic, and certainly nonmoldable tissue, the natural question that comes to mind is, "How did it obtain this positional relationship?"

To answer this question, we have postulated a theory using known facts to explain the entire process. If the adjacent cells form a permanent chemical bond (perhaps due to the hydrogen bonding ability of the base polymer) to the surface of the monofilament strands, then it is safe to assume that if either the adjacent cells or the monofilament strands move, the movement is likely to occur together. This, of course, is dependent upon slow movement. A sudden departure from any fixed position would result in the tearing of tissue or breaking the monofilament strands. Cells forming the basal layer of the skin are composed of germinating immature epithelial cells. A natural course of events is for these basal cells to migrate toward the surface, gradually losing their cuboidal form to become the typical eliptical form of mature squamous epithelium. Finally, these cells die and become the cornified outer layer. A basal cell which has attached itself to the surface of a receptive polymer would, as it matures, have the same tendency to migrate toward the surface. Vector forces applied to the monofilament strand in this manner gradually carry it to the surface. As the individual cells become the cornified layer, strands of the monofilament velour should be demon-

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strable as entrapments. Figure 6 is a photomicrograph of a biopsy site of nylon velour clearly showing monofilaments imbedded in the cornified layer of squamous epithelium.
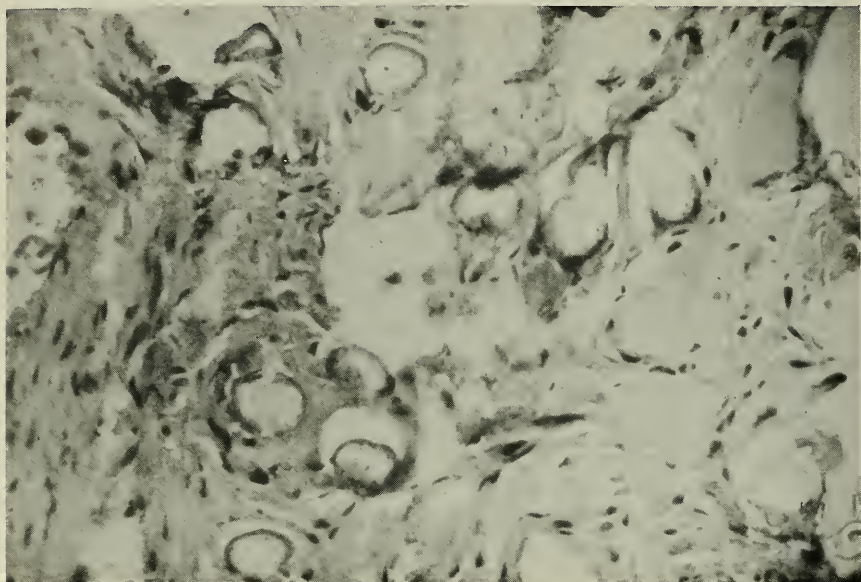
FIGURE 5.—Photomicrograph of implant site of velour fabric (nylon velour). The close relationship of the monofilament strands to adjacent cellular structure is apparent. The semilunar hiatus seen on one side of each strand is an artifact caused by the microtome knife encountering substances of varying mechanical impedance. Note that the hiatus is always on the same side—each strand having been pulled away from the tissue in the direction traveled by the microtome blade.

This would obviate a pessimistic outlook to the solution being sought if it were not for the fact that the maturation rate appears to be quite different at various anatomical sites. For instance, the site selected for these implants appears to be an order of magnitude greater than the ventral surface of the body. Why this should be true is conjecture, but it might have to do with the fact that the back is exposed to more direct rays of the sun and demands a more rapid sloughing rate than the ventral surface. A future experiment is planned whereby the implant procedure will be repeated but will alter the type of skin through which the test rod penetrates by first transplanting a full thickness homograft from the ventral surface of the animal to the dorsum and transplanting the excised dorsal portion to the ventral surface. Comparing the extrusion rates of these two implant areas should prove interesting.

Actual application of the velour technique to bring skeletal extension through the integument has not been impeded by the extrusion process.

This success might be explained on the basis of a short survival time, our longest being 14 months. Longer periods of time might expose extrusion problems. The skin maturation rate of the hind limb may be of the same order of magnitude as the ventral surface. In any event, the use of velour to create a bacteriostatic seal around the protruding skeletal extension has thus far been satisfactory and has presented no problems.
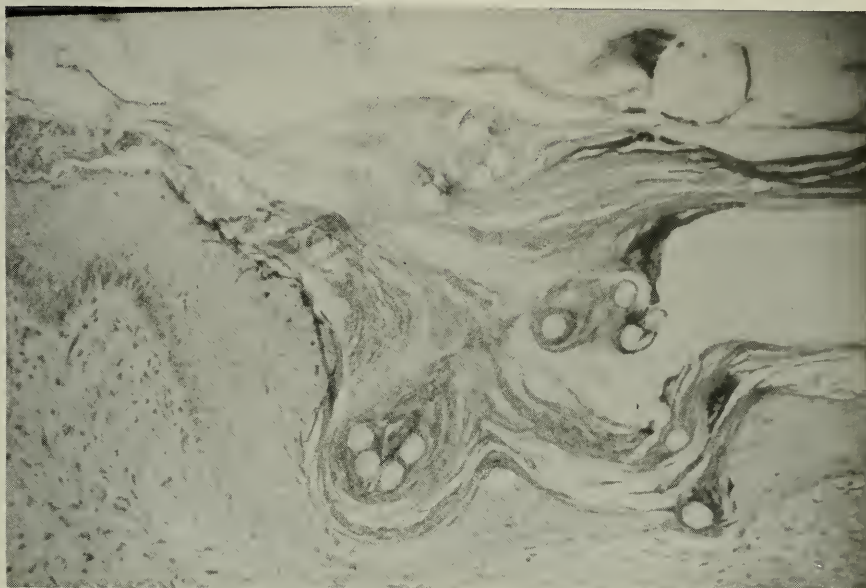
FIGURE 6.—Entrapped monofilament strands are demonstrable within the cornified layer. Natural migration of attached basal cells toward the surface during their maturation have carried the individual velour filaments along with them. This explanation postulates a permanent chemical bond between an adjacent basal cell and the surface of the polymer.

MUSCULOTENDINOUS SKIN INTERFACING

In order to bring the proposed alliance under direct control of existing skeletal muscles, a method is being proposed to couple the external articulating joint to the skeletal muscles using an artificial tendon. One end of the tendon would be sutured to the insertion end of the muscle. A skin-flap would be constructed to afford a bellow-type tunnel to accommodate the necessary travel and length change of the coupling. As the tendon exits through the tunnel end, a piece of velour fabric would be bonded to the artificial tendon's surface—thus preserving the bacteriostatic integrity of the skin. The distal end of the artificial tendon would then be mechanically affixed to the external prosthetic appliance.

Although all of the above appear theoretically possible, only portions have actually been attempted. A reel-type takeup to adjust tendon

tension has already been designed and fabricated into the articulating external device. An artificial tendon has been fabricated by modifying Dow Corning's original Silastic-covered Dacron tape. This modification consisted of sewing a triangular section of nylon velour to the proximal portion of the Dow Corning tendon (Fig. 7). The velour was sutured to the severed Achilles tendon of a goat: Holes bored into the calcaneus served to anchor the distal end of the artificial tendon. The velour presented a large surface area for fibrocytic ingrowth, adding strength to the union that would ordinarily depend upon simple sutures.

FIGURE 7.—Dow Corning's Silastic-coated tendon modified by sewing a piece of nylon velour to the proximal end. Fibrocytic ingrowth into the velour ultimately creates a union of such strength that the original sutures become unimportant.

This later experiment was designed to test the feasibility of developing a strong union between the artificial tendon and the musculotendinous portion of a strong skeletal muscle. Figure 8 shows an animal which has had the left Achilles tendon replaced by the method described in the preceding paragraph, The animal has no detectable limp, no contracture, and has complete freedom of motion as evidenced by her ability to maintain normal agility.

FIGURE 8.—Four months before this photograph was made, the Achilles tendon of the left leg was replaced by the artificial tendon shown in Figure 7. Agility was demonstrated by her ability to jump to the roof of her quarters just prior to the taking of this photograph.

A future experiment will be identical to the one described above, with the addition of developing a skin tunnel exiting to the exterior and penetrating the skin again near the proposed site of insertion. These experiments have been designed to prove the feasibility of anchoring an artificial tendon to its biologic counterpart with sufficient strength to maintain normal function and to prove the feasibility of bringing such a tendon to the exterior. No amputation of the limb is required for these studies.

BONE INTERFACING

The basic structure of the skeletal extension is an intramedullary rod driven into the amputated distal end of the goat's tibia. A polypropylene cone molded to the rod serves both as a weight-bearing pedestal and as a bond for the nylon velour to which the skin is sutured. Recently, this plastic cone has been redesigned to fit a mortice made in the tibia at the time of amputation (Fig. 9). This prevents rotation of the shaft and transmission of shear forces from being applied to the interface.

Transferring the forces of weight-bearing directly to a skeletal extension demands near perfect interfacing between the artificial device and the natural bone. Shear forces develop all along this interface and must be equally distributed over as wide an area as possible. Material selection for this interface should have an impedance match that would maintain the integrity of the interface.

FIGURE 9.—A polypropylene cone molded to the shaft of the skeletal extension rod serves to accept the weight-bearing end of the tibia and to act as a bond for the velour fabric used to interface with the skin. In order to prevent torque to the shaft from being transmitted to the interface between the shaft surface and bone, a mortice between the cone and tibial end has been created.

To date, three types of interfacing have been tried. The first was a simple close fit using a sandblasted Vitallium rod. Eventually these rods became loosened by resorption of bone at the interface and replacement with a gelatinous layer of collagen. When this occurred, the pull strength of the device was severely weakened.

A second method was to use a metalic rod (either Vitallium or stainless steel) similar to the one described in the preceding paragraph but having lesser tolerances between the diameter of the rod and the intramedullary canal. Voids between the rod and the canal were filled with plastic adhesive (Surgical Simplex, North Hill Plastics, Ltd., London, England). For periods up to 7 months, this technique proved satisfactory. Late failures appear to be related to chronic osteomyelitis which could possibly be due to contamination of the surgical adhesive during mixing or to a break in aseptic technique during surgery.

A third method of establishing an interface with bone was to use porous ceramic as an outer surface on the intramedullary rod. Details of this construction were described in a previous report. Most of the failures using this technique were mechanical in nature (Fig. 10). Success depends upon new bone ingrowth into the porous ceramic (Fig. 11).
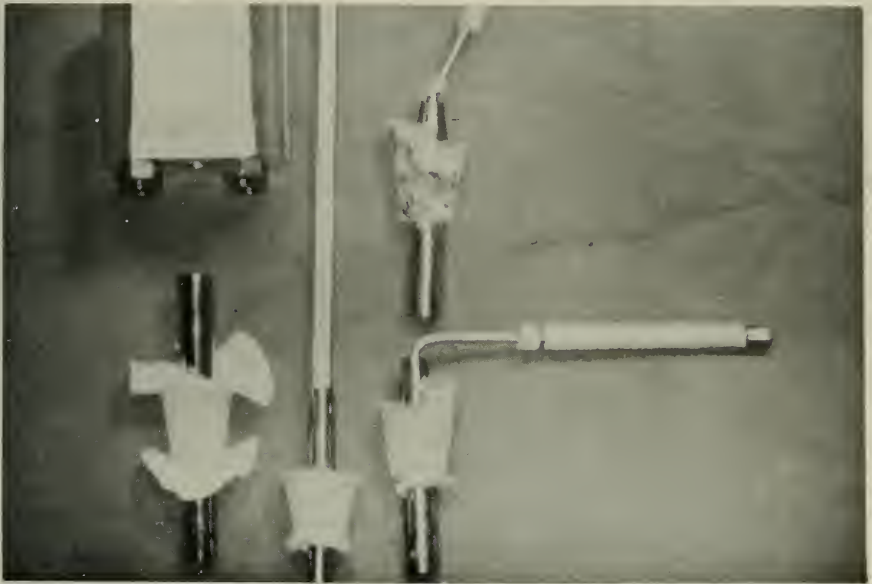
FIGURE 10.—Intramedullary rods. Top left is mold used to fabricate velour-covered pedestal shown at bottom left. Center rod made of stainless steel shows earlier form of the polypropylene pedestal. Later forms shown on the right have stair-stepped surface to accept morticed end of tibia. Mechanical failures of two of these devices are evident.
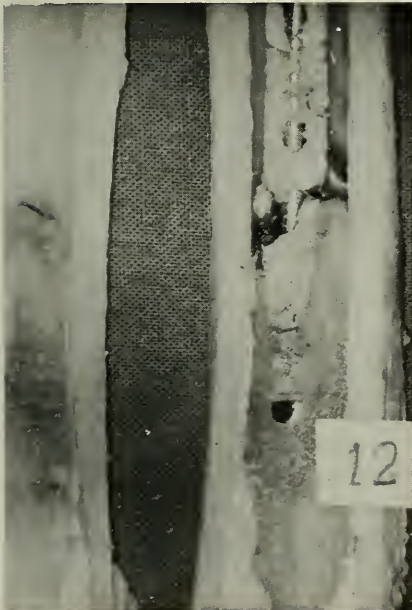
FIGURE 11.—Cross section cut through tibia exposing intramedullary rod, ceramic sections, and new bone ingrowth. New bone growth is more rapid at the distal end with no osteogenesis occurring at the isthmus. This is probably due to the anatomy of the circulatory system of long bones.

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In all of these cases, velour has been permanently bonded to the surface of the pedestal which in turn serves as the interface for soft tissue ingrowth. A small skirt of velour at the distal base of the pedestal serves to anchor the skin (Fig. 12).
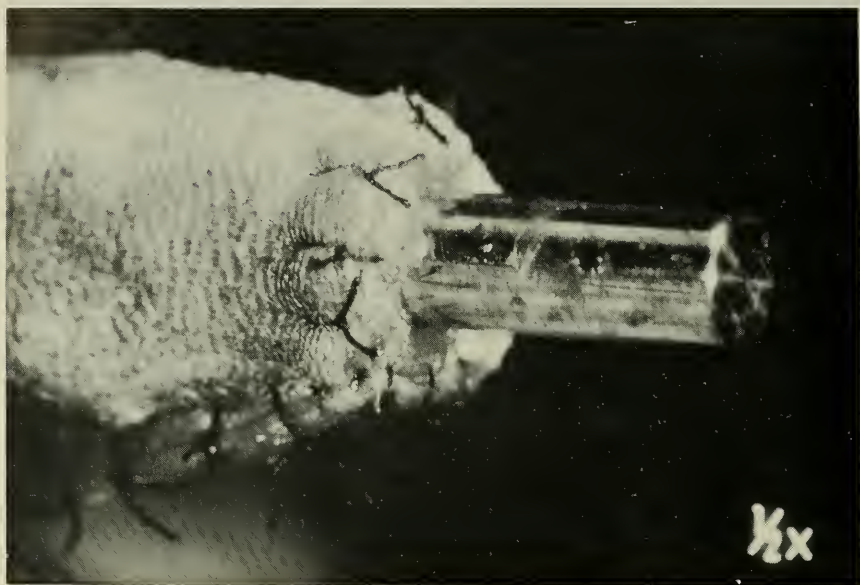
FIGURE 12.—Closeup of skin closure showing how interrupted sutures are used to approximate the skin edge to the velour skirt contained at the base of the pedestal.

EXTERNAL APPLIANCE

To date, only limited attention has been paid to the design of the external portion of the prosthetic device. An articulating structure having two reel-type takeup devices to adjust tendon tension has been designed. This remains untested since the tendon part of the research project is lagging. Most of the goats, having undergone amputation with implantation of an intramedullary extension, have had a simple pylon affixed to the projecting end. These have served well to test the skin and bone interfaces, and test animals quickly learn to use them without difficulty (Fig. 13).

FIGURE 13.—Close inspection of the new leg apparently meets with approval.

SUMMARY

A permanently attached artificial limb is an achievable dream within the foreseeable future. The problems remaining to be solved are the interfaces which need to be maintained between the prosthetic device and bone, and between the prosthesis and the skin through which it protrudes. The interface between the bone of the limb and the metal rod placed in the medullary cavity is well on the road to solution by permitting bone ingrowth into a porous ceramic coating on the metal rod. The skin interface is a more difficult problem which we have approached through the use of nylon velour. This has thus far eliminated the problems of marsupialization which characterize the use of biocarbon interfaces and of extrusion as seen in some of our experimental rod implants. Bacteriostatic seal with nylon velour skin interface has been so good as to encourage our use of this same mechanism for artificial tendon and skin interface as we experiment with a means for connecting the muscles of the limb to the external portion of the prosthesis.

THE DEVELOPMENT OF ARTIFICIAL LIMBS FOR LOWER LIMBS

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INTRODUCTION

This project represents a continuous effort of Mauch Laboratories toward the improvement of artificial limbs, particularly for the lower limbs. Work on five items has been underway: A semivoluntary Swing and Stance Control knee mechanism (S-N-S System), an automatically controlled Tri-axial Ankle mechanism, a fully Voluntarily Actuated Swing and Stance Control knee mechanism, a mechanical low-cost version of the S-N-S System for short-term use and for geriatrics, and a novel cosmetic cover for above-knee prostheses and for a tri-axial ankle mechanism.

FEATURES OF THE S-N-S SYSTEM

This system is basically a hydraulic cylinder-piston device. Its swing control part uses our patented design in which exit holes for the hydraulic fluid in the cylinder wall are progressively covered by the advancing piston, in both the flexion and extension direction, leaving fewer and fewer holes open, thus increasing the swing resistances in a pattern determined by the location of the exit holes. The patent covering this design was assigned by us to the Veterans Administration many years ago, and the design was adopted by the other two manufacturers of hydraulic swing control systems (Hosmer and U.S. Manufacturing Company) through a royalty-free license agreement. It is estimated that today more than 10,000 knee-control systems are based on this patent.

The stance control of the S-N-S System uses our so-called hyperextension control principle, which prevents buckling by providing a high weight-bearing flexion resistance about the knee joint at all times, except during the flexion portion of the swing phase for which it is eliminated by a preceding hyperextension moment about the knee joint of at least 1/10th of a second duration. This moment is automatically provided in walking by the ball pressure shortly before toe-off.

The moment can also be produced voluntarily by pressing the stump backward for a short instant immediately before flexion, allowing jackknifing stair or ramp descent, sitting down quickly, etc.

The stance-control function can be eliminated by a switch to permit bicycling, rowing, etc. The same switch can also be used for locking the leg fully against flexion for activities such as operating the gas pedal of a car, etc.

DEVELOPMENT OF THE S-N-S SYSTEM

The S-N-S System has been in production since 1969. More than 3,000 are in use today. During these years, a great number of improvements (more than 50) have been incorporated in it on the basis of field experiences. This resulted in the elimination of noises, reduction of energy consumption caused by undesirable friction, change of its geometry and its resistance profiles to conform to the VA setup standardization, and extension of its initial maintenance-free lifespan from an average of 1 year to the present 2-year average. All this enabled us to go to a 12-month guarantee a little over a year ago.

During the last contract year, a very significant improvement was added, the so-called dynamic self-bleeding feature which eliminates automatically by walking motions any air which might have found its way into the hydraulic working spaces. (Such air causing erratic resistance patterns and noises.) This important feature and some of the other improvements mentioned are adaptable to the hydraulic systems of other manufacturers. Our progress reports contain basic information on these design ideas, and we are prepared to assist any interested manufacturers in adopting them. There are no patents involved here.

As to the future of the S-N-S System, we stated in our next year's contract proposal that, "We are not aware at the present time of any specific shortcomings which would call for further improvements." We are convinced that any as yet undiscovered shortcomings will be minor. At the request of VA staff personnel in New York, we will now update the so-called "Bible," which was started approximately 10 years ago, for our swing control ("B") system, by including all necessary stance-control information to enable any qualified manufacturer to produce the S-N-S System if the need should arise.

DEVELOPMENT OF A MECHANICAL VERSION OF THE S-N-S SYSTEM

A prototype model of a simple swing-control device based on mechanical friction was designed and built early this year. The device can be exchanged for any of the standardized hydraulic or pneumatic swing-control systems, including the S-N-S System, in pylon-type or in wooden legs while the systems are being repaired, and it may be an economic alternative for these systems in temporary prostheses and in the case of geriatric amputees who might not use the full potential of the more

expensive systems. Its design is based on the well-known principle of a step-wise progressive engagement of mechanical friction elements, such as used in the Northwestern above-knee setup and in an early Navy design. It differs from these precedents by having a total of nine steps for producing an almost continuous friction profile and by a longitudinal rather than rotational working principle which permits its use as a replacement for a cylinder-piston device.

The device was test worn by our amputee and worked as expected. The cost of this device is very low because punched plastic parts are used almost exclusively. The design permits further development to include a mechanical locking device for automatic buckling prevention based on the hyperextension control principle of the S-N-S System.

The swing-control device was shown to our local prosthetist and to Dr. Murphy. The consensus reached in these demonstrations was that the inclusion of the stance-control feature is essential for making the mechanical approach worthwhile. This development will be continued on a low priority basis.

FEATURES OF THE HYDRAULIC ANKLE

The functions of this artificial ankle (Fig. 1) must duplicate as closely as possible, within the weight, space, and price limitations, the functions of the natural human ankle around all three spatial axes:

a. *The Medio-Lateral Axis.* A hydraulic vane-type piston which moves in a housing through a range of about 30 degrees, provides toe-slap damping, and toe pickup. The most important feature of this new ankle is a variable dorsiflexion stop which adapts itself automatically in every step to the changing upward-downward inclinations of the walking surface (see Fig. 2). Toe-slap damping and toe pickup are not shown in this schematic drawing. Its purpose is to illustrate the control principle used for the automatic adapting of the dorsiflexion stop. The piston rod (1) is attached to the shank, and the housing (3) to the foot of the prosthesis. The vane-type piston (2), which is part of the piston rod and therefore of the shank, rotates about the bolt (4) which is attached to the housing and therefore to the foot. The housing is filled with hydraulic fluid which is contained by the rubber boot (5). The vane-type piston has a port (8) which connects the chamber behind the piston with the chamber in front of the piston. A ball (6), which is guided by the cage (7), but can roll freely forward and backward on the bottom of the housing, will always tend to seek the lower-most point. The port (8) in the piston is so arranged that the ball (6) will close it on contact and prevent fluid flow from the rear chamber to the front chamber, thus blocking dorsiflexion of the foot. Contact will occur whenever the piston rod and therefore the shank are vertical, no matter whether the housing and therefore the foot are inclined downward or upward or are horizontal. This means that in

walking uphill the dorsiflexion stop will occur later than in a standard ankle which eliminates the need for the so-called "pole-vaulting," and that in walking downhill the dorsiflexion stop will occur sooner than in a standard ankle which prevents knee buckling. A bypass (9) through the piston is closed by a valve (10) and valve stem (11) whenever the amputee steps on the leg. It opens upon weight removal which permits the return of the foot to its normal position relative to the shank under the influence of springs which are not shown.
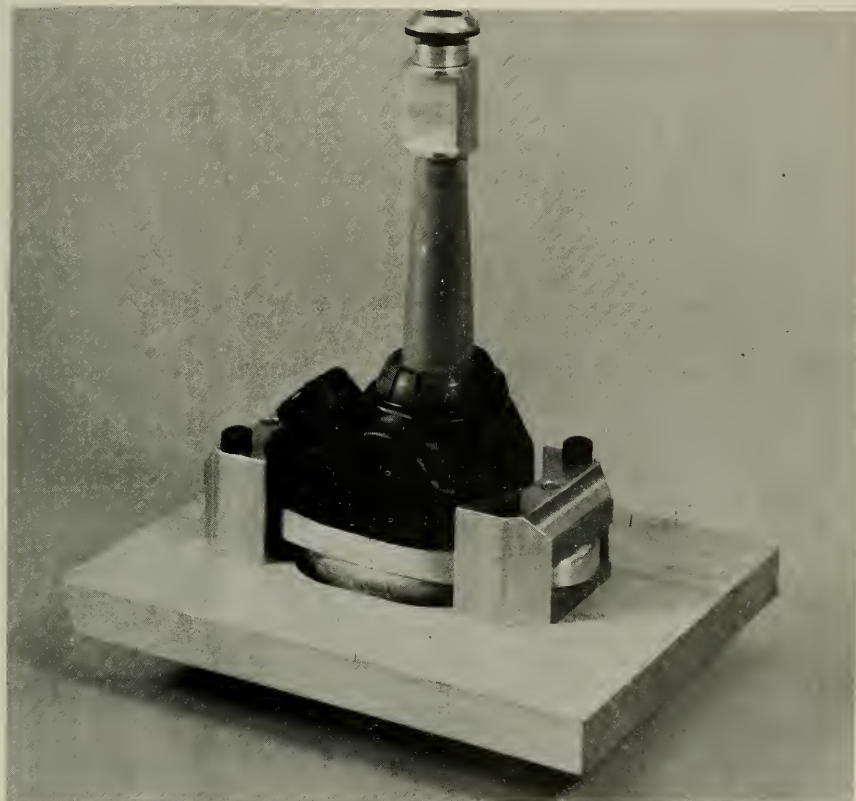
FIGURE 1.—Hydraulic Ankle Control Unit mounted on a baseboard.

b. *The Anterior-Posterior Axis.* Eversion-inversion control is achieved by the way the front pad and rear pad of the ankle housing are attached to the foot. Exchangeable rubber pieces which are interposed between these pads and two attachment yokes within the foot come in shapes which the prosthetist can arrange to produce either elastic yielding in the eversion *and* inversion direction, or in the inversion direction only, or in neither direction. We prefer the second alternative which yields medially but provides lateral stability.

c. *The Vertical Axis.* Transverse rotation control is achieved by the way the piston-rod tip is attached to the shank. Again as in the previous point exchangeable rubber pieces, which are interposed between the flat side surfaces of this piston rod tip and corresponding parts inside the shank, come in shapes which the prosthetist can arrange to permit either elastic forward *and* backward rotation of the pelvis during the stance phase, or forward rotation only, or rotation in neither direction. Again we prefer the second alternative which provides more freedom in striding out without backsliding of the pelvis at the initiation of a step.

THE DEVELOPMENT OF THE HYDRAULIC ANKLE

The development of this device was often interrupted by higher priority work and was delayed several times by test findings which called for major redesigns. The design was unusually difficult for the following reasons:

a. The design space available is very limited. We do not know at present what minimum foot size can be accommodated, but we do intend to include as many as possible in the women and adolescents' sizes.

b. The weight of the device must be as low as possible because of its location at the most distal end of the artificial leg, which gives its mass a maximum momentum. We compared the weight of two identical lower legs, one with a single bolt ankle joint and the other one with our hydraulic ankle, and found that the weight increase is only approximately 2½ oz.

c. During walking and especially running, the device is subject to severe pounding particularly on hard ground. This must not damage it.

d. In walking through sand or puddles, the danger of contamination and corrosion exists and must be counteracted by the design.

e. Severe temperature variations are possible at a location so close to the ground, in walking through ice and snow or on hot pavement. These variations must not impair the proper function.

f. All functions must be practically noiseless, which sounds much simpler than it is.

g. In spite of all these requirements, the device should last at least 2 years without maintenance, except for the occasional exchange of external spare parts.

h. Last but not least, the price of the device should not be excessive, i.e., not over $150.

In order to achieve all these goals the Ankle underwent a drastic redesign during the past contract year. This was prompted by test findings during initial shakedown testing by three different amputees. The redesign was completed and two prototypes were built using patched-up existing parts. The prototypes are presently being test worn by our own amputee and an amputee in the New York area. A third

WALKING DIRECTION
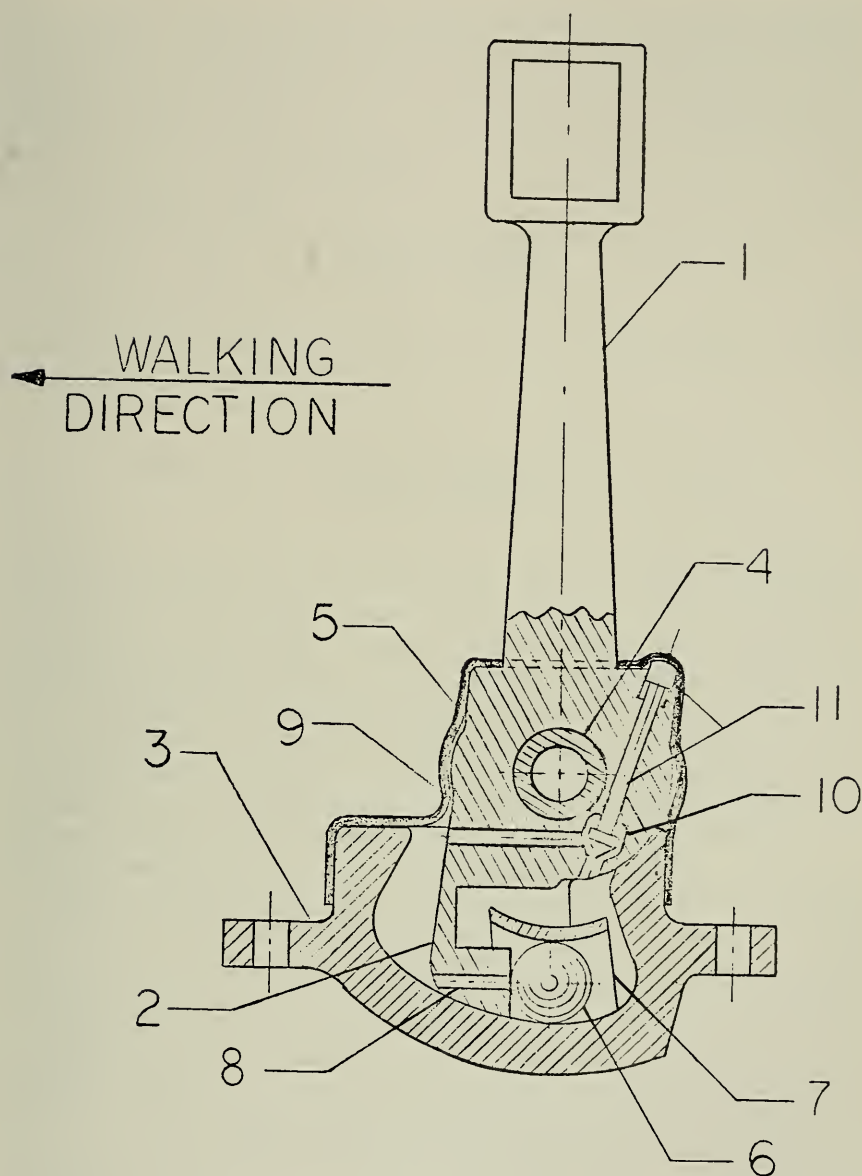
FIGURE 2.—Hydraulic Ankle Control Unit, schematic.

prototype is being built as a spare. The acceptance of this redesigned ankle by the test amputees was excellent. All the functions are exactly as planned. The noise is below the tolerance threshold.

The work ahead includes the following: At least five more amputees must be equipped with ankles to learn about variations among the

amputee requirements. At least one below-knee amputee must be included. The additional ankles needed for these amputees must not be made from patched-up existing parts but from final parts. This calls for a certain redesign involving new casting patterns and a new rubber mold for the U-seal. In the meantime the tests must continue to reveal about possible noises, symptoms of wear, and maintenance problems. Any findings in this respect may lead to the need for design modifications.

In our proposal for the coming contract year we stated, "The continuation of this work will constitute our highest priority effort during the contract period. . . . We will attempt to push this project sufficiently to come up with an ankle ready for field testing by the end of this contract year." We feel that eventually the hydraulic ankle will advance prosthetic ankle joints as much as hydraulic knees advanced prosthetic knee joints.

FEATURES OF THE VOLUNTARY SWING- AND STANCE-CONTROL SYSTEM

Voluntary control of the above-knee prosthesis has been the goal of designers for decades. In spite of the advances made in recent years, present above-knee prostheses still limit the activities of an amputee substantially, forcing him to conform to the built-in response patterns of the prosthesis rather than allowing him to vary the pattern to fit the situation. This applies even to the semivoluntary S-N-S System.

A simple method of giving the amputee control of the yielding rate in the stance phase would increase stumbling safety and would open up a much broader area of physical activity than is available to him now. Such everyday activities as descending ramps or stairs could be performed in a much more natural way and if, in addition, it were possible for the amputee to lock the stance control at will, an even wider range of activities including athletics would become available to him. Moreover, locking the stance control, but at the same time providing a degree of resiliency about the knee joint, would enable him to execute the so-called double knee bend after heel-contact, resulting in a more natural gait. This is not feasible in a nonvoluntary system because, to avoid energy dissipation during the double knee bend, full lock is required and full lock in a nonvoluntary prosthesis is potentially dangerous.

Any voluntary control of the yielding rate in the stance phase could also be adapted to control the flexion resistance during the swing phase in a voluntary way. This would provide the amputee with a cadence control far superior to the programed cadence control of present swing-control systems. Voluntary swing control would be very helpful in sports activities (you could kick a football) and would even permit dance steps. Control of the extension portion of the swing phase to provide a variable terminal deceleration could also be made an integral part of a voluntary control system.

To exploit these potentialities fully the amputee has to be kept informed about the position of the shank relative to the thigh by a feedback. This position feedback will supplement the stump pressure feedback from the socket.

These were the considerations and the resulting features which we set out to achieve almost 10 years ago.

DEVELOPMENT OF THE VOLUNTARY SWING- AND STANCE-CONTROL SYSTEM

As usual, the road has been an arduous one with many interruptions and delays due to the difficulties of the problem and because of other higher priority work.

It was clear from the beginning that a hydraulic-cylinder-piston device would be used for controlling the knee joint. It was also clear that this device would not pose serious problems and in fact would be much simpler and less expensive than the S-N-S System. So we worked on its design over the years whenever there was some time available. Then we built the parts which we will assemble as soon as our workload permits.

It was also clear from the beginning that there are a number of relatively straightforward ways to feed back to the amputee information regarding the knee angle. We plan to use a low-frequency vibratory or galvanic signal acting on the posterior stump surface. Increasing frequency will indicate more knee flexion. In order to save battery life and avoid numbness of the skin there will be no signal when the leg is fully extended, such as in standing and when it is flexed beyond 70 deg. as in sitting and kneeling. The hydraulic system mentioned before contains a potentiometer which will provide this kind of feedback.

Finally, it was clear from the beginning that the really crucial problem was how to obtain from the amputee a control signal which would enable him to produce a gradual scale of at least four distinct control states and to do this approximately one million times per year with sufficient reliability to avoid accidents.

Since myoelectric control was coming of age during these years and seemed a natural choice, we consulted many workers in that field, including Robert Scott, from whom we purchased one of his three-state devices; Childress, Wirta, Taylor, and Finley, who were kind enough to visit us in Dayton for this purpose; and Reswick, Ko, and Mooney. We also conducted for a time myoelectric in-house research and studied all the reports we could find. As a result of these efforts, we became convinced that myoelectric control of a lower-limb prosthesis, using skin contact electrodes, was not safe enough.

Because of these doubts we also investigated the use of ultrasonic echoes from a muscle as a signal source. The results were disappointing. We then conceived and designed a vibrating-muscle hardness sensor,

which might work but is somewhat complicated.

A basically simpler solution may be the so-called bio-carbon buttons developed by NASA and adopted by Reswick and Mooney of Rancho Los Amigos for transmitting signals into the neuromuscular system. As a result of their cooperation and encouragement, we are considering these carbon buttons for obtaining a more reliable myoelectric signal from the amputee's stump. Without any internally attached wires these buttons will reduce the percutaneous impedance by up to 90 percent as compared to skin contact electrodes. This would make the influence of electrical outside interference or of perspiration negligible. The buttons can be inserted by any qualified doctor in his office under local anesthesia in a few minutes. Healing takes place in a few days. The buttons have remained in the skin of subjects for over 3 years without infection or irritation. They are practically flush with the skin surface and do not interfere with skin care. The hydraulic system mentioned before contains an electromagnetically operated throttle valve, which will be controlled by the signal derived from the carbon buttons or from the muscle hardness sensor.

We believe that we now have all the ingredients for a voluntarily controlled knee joint, and that this development will eventually open up a new chapter in the rehabilitation of above-knee amputee.

LOCOMOTION AND LOWER-LIMB PROSTHETICS

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INTRODUCTION

One of the principal activities of the members of the Biomechanics Laboratory during the past two decades has been the study of human locomotion. A major objective of these studies has been the accumulation of data that might be used in the design and construction of improved prosthetic and orthotic devices. The investigations have included electromyograms of the phasic action of muscles, forceplate recordings of floor reactions in both normal subjects and amputees, recordings of angular displacements and angular accelerations using a variety of techniques, and measurements of metabolic energy expenditures of normal subjects and subjects with various encumbrances, such as loads applied to certain segments of the body or devices to immobilize certain major joints. Amputees wearing various types of protheses have been evaluated by a variety of techniques. Some of the material obtained from these studies has been published in journals, reported at various scientific meetings, or preserved in technical reports with limited distribution.

When the vast amounts of data are reviewed, two facts are evident. First, the major displacements of the hip, knee, and ankle are grossly similar in all people and clearly are the result of our bipedal orthograde type of locomotion. Second, the variations in the less apparent movements are great, for example, in the horizontal rotations of the pelvis, thigh, and shank and the motions of the ankle and intrinsic articulations of the foot.

These latter movements play a major role in determining the unique characteristics of an individual's gait which enable one to recognize a friend walking even at a distance. Furthermore, these individual differences may be of great importance in orthopedic surgery and in the proper prescription of new prosthetic and orthotic devices.

Despite the wide range of anatomic variations which exist and disabilities which may be involved, there is in most individuals a remarkable

ability to integrate any remaining locomotor assets into a relatively smooth-functioning whole. Compensation for disability at a specific joint frequently is possible by modifying the way in which adjacent joints are used. This implies that there must exist between the various articulations certain interrelationships which are complementary or compensatory. A better understanding of these relationships is essential for improved rehabilitation of people with locomotor disabilities.

Any analysis of the compensatory relationships which exist in walking demands simultaneous examination of many variables. Experience has shown that visual examination of walking is not enough; the many interrelated motions of walking are too numerous and occur too quickly for the eye to follow in detail. This realization has underlain all of the locomotion studies of the Biomechanics Laboratory and, in particular, has had a fundamental influence on the current project, in which computers and specialized electromechanical devices are being applied to permit simultaneous measurement of 20 or more relevant variables of walking. Suitably displayed, such measurements can effectively supplement visual impressions and can assist in the diagnosis and treatment of gait disability.

The sections which follow summarize recent progress in instrumentation and biomechanical studies, as well as progress in the design and development projects which provide motivation for the fundamental studies.

BIOMECHANICAL STUDIES OF HUMAN LOCOMOTION

1. Instrumented Walkway

Limitations of Treadmill

Preliminary studies have shown the importance of considering the whole range of available walking speeds when analyzing gait. These studies have been conducted on a treadmill in order to simplify instrumentation and to avoid the expense and additional complexity of telemetry. It has never been questioned, however, that many types of gait studies cannot be conducted satisfactorily on a treadmill. Although most normal subjects quickly learn to walk comfortably on a treadmill, some never do, and the treadmill cannot even be seriously considered for subjects with serious gait disabilities. Consequently, plans to apply the same, or similar, measurement techniques to the walkway have been underway for some time.

Wires vs. Telemetry

The dimensions of the current laboratory allow a walkway approximately 9 m. (29 ft.) long. A longer walkway would be desirable, but this length was judged to be acceptable for the time being. On this relatively

short walkway, direct attachments by wires to instruments on the subject are being used. For those studies which require only a small number of wires, the cable is trailed behind the subject or supported by a passive cable trolley. Any further expansion of gait studies to more complex instrumentation, to longer walkways, or to outdoor environments will be accomplished with the aid of telemetry. Preliminary planning for a 16-channel pulse-code-modulated telemetry system is underway.

Distance Measurements

The principal difficulty in instrumenting a walkway lies in the measurement of the position of the subject along the walkway in order to compute step length, one of the fundamental variables of interest. A closed loop string, such as that used by Drillis (1) in his Tachograph, was considered, but has not been built because of the difficulties involved in allowing the subject to turn around easily and walk the other way. The use of Doppler radar, similar to that used to detect speeding automobiles, offers great promise, but it has been avoided for the present because of the time and expense which would be required for development. The technique which has been selected for initial studies is the common one of positioning two (or more) light beams across the walkway at known distance intervals and detecting interruption of the light beams. A measurement of the time between interruptions allows computation of an average velocity, which together with measured step durations permits computation of average step length. The step durations provide a means for detecting nonuniform progression along the walkway.

The photo-device selected is a commercial unit which contains both infrared light source and detector. This construction simplifies installation because all wiring is on one side of the walkway; only a plastic retro-reflector need be placed on the other side of the walkway. Two pairs of simple tubular supports were built and attached to the floor 4 m. apart. These supports provide simple height adjustments which allow the light beam to be positioned just below the chin of the subject, the level which was judged would provide the smallest errors due to movements of head or limbs. The outputs of the photo-devices have been modified to provide pulses which can be fed directly to the computer.

Conductive Walkway

The walking surface of the walkway consists of a length of conductive rubber conveyer belting. This material is smooth and provides an excellent nonslip walking surface. The conductivity of the rubber is sufficient to allow electrical detection of foot contact.

2. Cyclic Event Markers

Step Events

As mentioned in earlier reports, reliable detection of contacts of the foot with the floor has been the most persistently vexing problem involved in computerizing the measurement of gait. The superposition of successive walking cycles is a valid technique for determining an average, or typical, gait pattern only if successive cycles are superimposed in proper relation to one another. If they are offset, the averaging process unquestionably will confuse, rather than enhance, the data. Consequently, the effective use of computer averaging techniques for locomotion data enhancement is totally dependent on the ability to detect, automatically and reliably, the occurrence of some representative event in the walking cycle. Heel contact usually is the event chosen to define beginnings and endings of steps, but scuffing of the heel, which inevitably occurs part of the time, results in multiple heel contacts which can destroy the precision of cycle time measurements and data averaging.

In view of the absolute requirement for reliable cyclic event markers, events other than heel contact have been considered. The most promising appears to be midswing, defined as that instant when the swinging ankle passes the stance shank. This event has been used by the BioEngineering Unit at the University of Strathclyde in Glasgow in their reduction of cine film data. Midswing can be detected more precisely than heel contact in cine records because it is the period of maximum velocity of the swinging foot, whereas heel contact is a period of low velocity. This feature of midswing which makes it a desirable event marker for cine data also makes it desirable for computerized data acquisition. Unlike heel contact, midswing occurs only once per step and its time of occurrence can be defined with millisecond precision. Techniques are now being examined which may make it feasible to use midswing instead of heel contact to control the acquisition of data by the computer. Foot contact information is still of great interest, of course, but it need not be of such great precision or reliability as before.

Heart Events

In the documentation of gait variables, measurements of metabolic energy expenditure often are of interest. Unfortunately, the available methods of measurement are either very tedious or very expensive. The physiology literature includes a number of experimental reports which suggest that, for an individual, heart rate may be a good indicator of relative energy expenditure (2, 3, 4, 5, 6). Correlation with absolute oxygen consumption is poor, but changes in heart rate generally correlate well with changes in oxygen consumption for the same person.

In view of these encouraging data and the desirability of energy

measurements—even relative energy measurements—for evaluation of devices or procedures, instrumentation has been designed and built which detects the electrocardiogram and produces a computer - compatible output pulse at each heartbeat. These pulses permit the appropriately programed computer to compute and display heart rate. Preliminary results tend to support the literature, although considerable testing will be required before a thorough analysis can be provided of the practical usefulness of heart rate measurements for gait evaluation.

Different heart rate displays are available for different purposes. The computer drives a strip-chart recorder for long-term monitoring (Fig. 1), graphical summaries are obtainable on a Tektronix terminal (Fig. 2), and a numerical summary is included in the standard step-dimension data summary sheet (Fig. 3). The two latter displays were modifications of earlier output formats, and although extensive programing was required for the original plots, the modifications were accomplished quickly. This is a good example of the way careful programing can result in ever-increased versatility of the computer system.
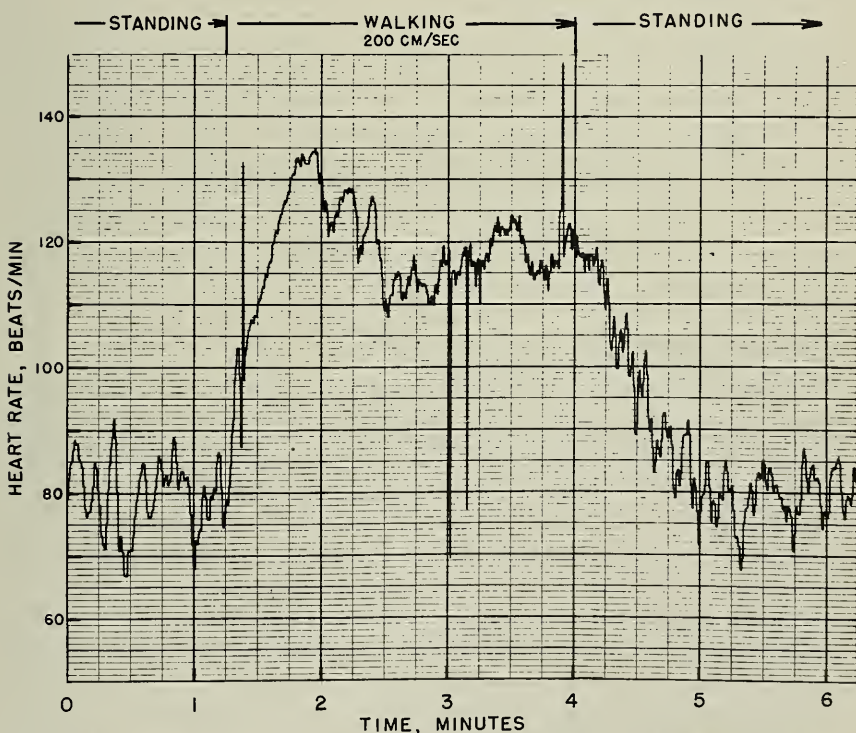
FIGURE 1.—Strip-chart record of heart rate for visualization of long-term trends.
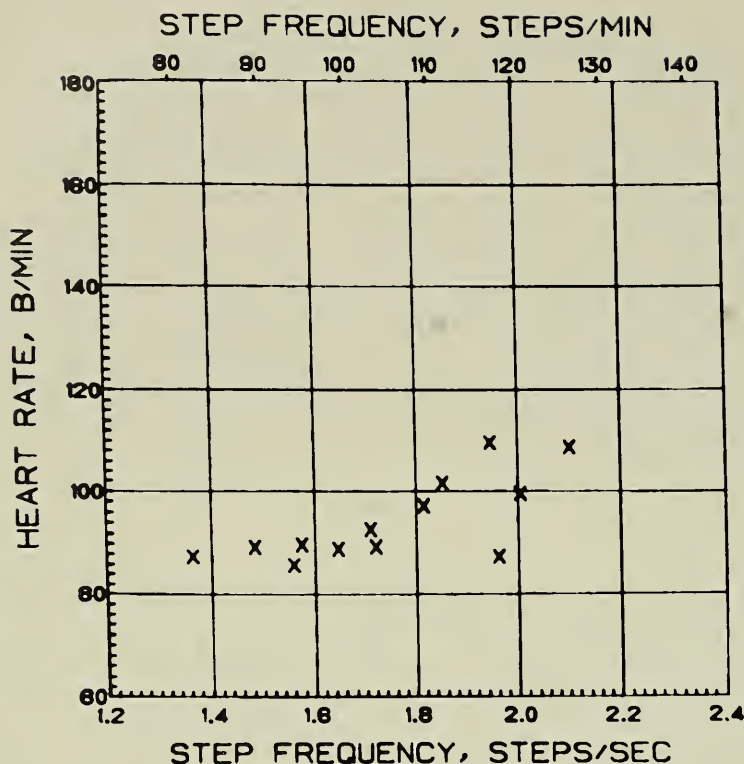
FIGURE 2.—Graphical summary of heart rate data.

3. Forces and Moments in the Lower Limb

A shank force and moment transducer has been completed, together with its 6-channel portable preamplifier, and tested on an above-knee amputee as shown in Figure 4. The computer data acquisition, data reduction, and automated graphical display give complete results in one day. Selections from these results are in Figures 5 through 8. Good sensitivity and zero stability were obtained for all channels, and cross-sensitivity was small for all channels except axial force, which was influenced to a significant degree by anteroposterior and mediolateral bending moments. Such cross-sensitivity is difficult to avoid in tubular pylon force and moment transducers because strains in the pylon due to bending moments are approximately eight times as large as those due to axial load. Computer corrections for the cross-sensitivity are feasible, but other types of transducer designs are being examined in the hope of

developing a practical and precise transducer which does not require cross-sensitivity corrections.

4. Self-Aligning Goniometry

Electrogoniometry is an appealing technique for measurements of walking, because measurements of relative motions at joints can be obtained directly without the need for subsequent data processing of any kind. Unfortunately, conventional electrogoniometers have been limited in their applications by the fact that their precise application depends upon precise alignment between goniometer axis and anatomic joint axis. At hip, knee, or ankle, precise alignment between a goniometer and the anatomic joint is difficult to determine or maintain, so goniometric measurements are of questionable accuracy at these joints.

```
              STEP DIMENSION DATA

   SUBJ: 24     HT: 184 CM    WT: 73 KG
   NO. OF STEPS: 32       FILE: 2


                 MEAN    UNITS    C.V.(%)


   LENGTH/FREG    424   MM×S

   STEP FREQ     1786   .0%1 STEPS/S

   HEART RATE     983   .1B/M     4.22

   VELOCITY      1237   MM/S      1.12


   STEP LENGTH    725   MM        1.13

        L         724   MM        1.24

        R         726   MM        1.00


   STEP DUR       586   MS        1.29

        L         584   MS        1.32

        R         587   MS        1.21
```

FIGURE 3.—Statistical summary of step dimension and other basic data from a typical data-collection run.
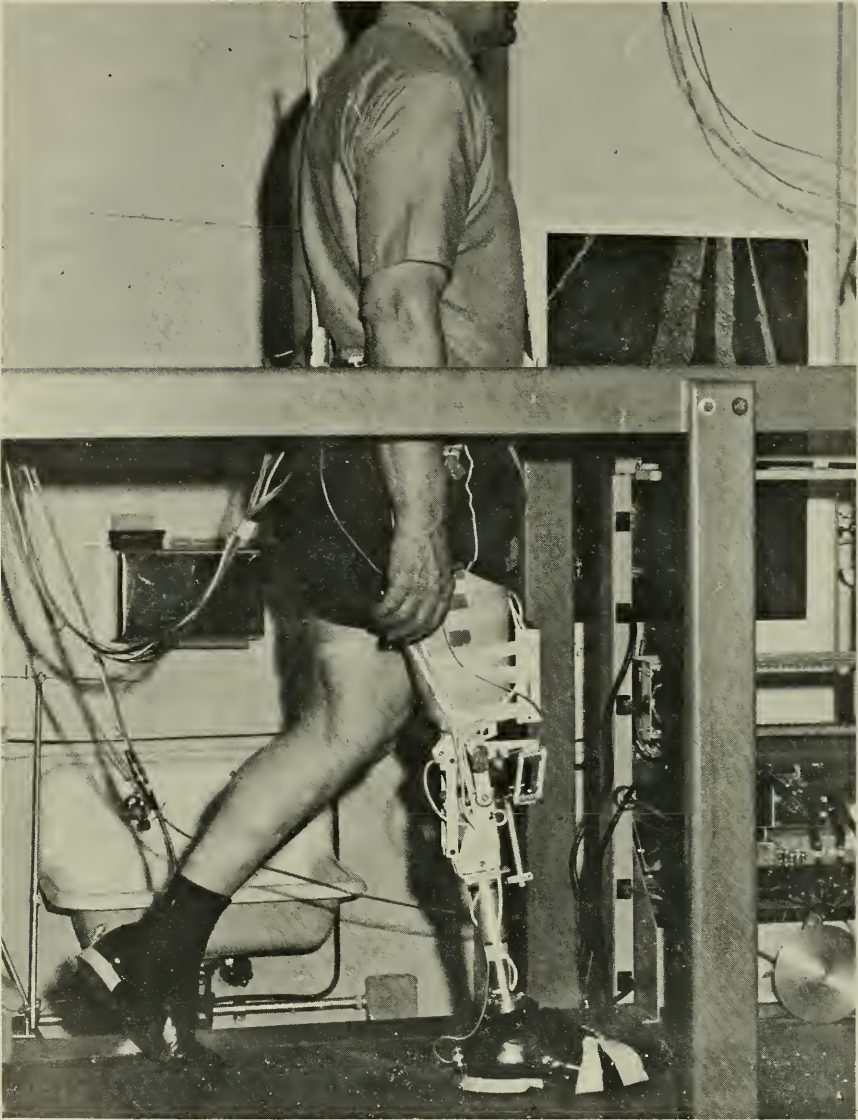
FIGURE 4.—Above-knee amputee wearing instrumented Four-Bar Polycentric Knee for force and motion analysis.
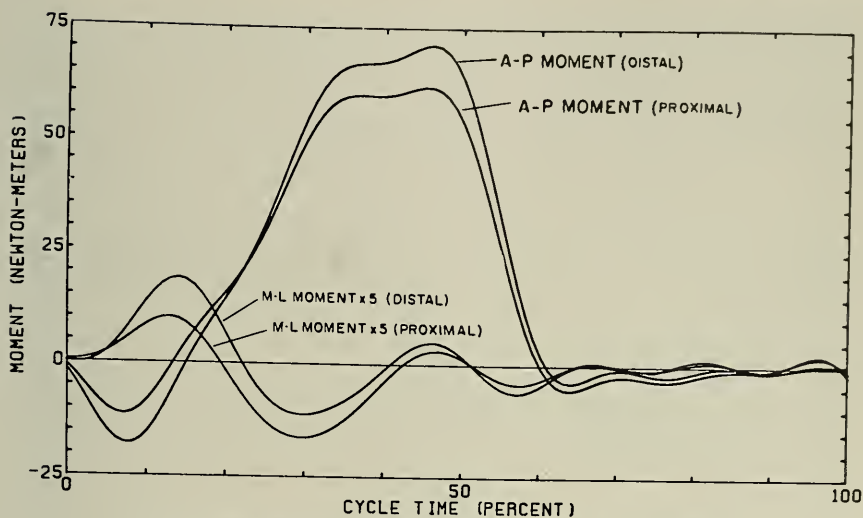
FIGURE 5.—Measured pylon bending moments (1.6 steps/sec.).
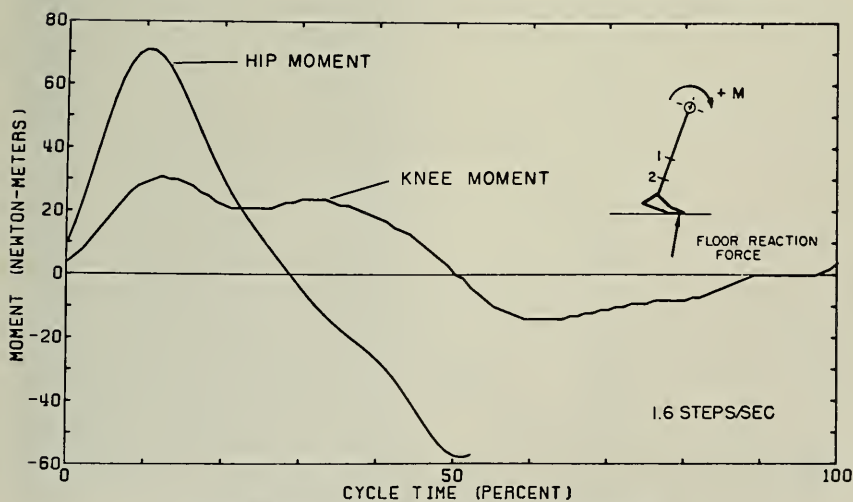
FIGURE 6.—Computed knee and hip moments.
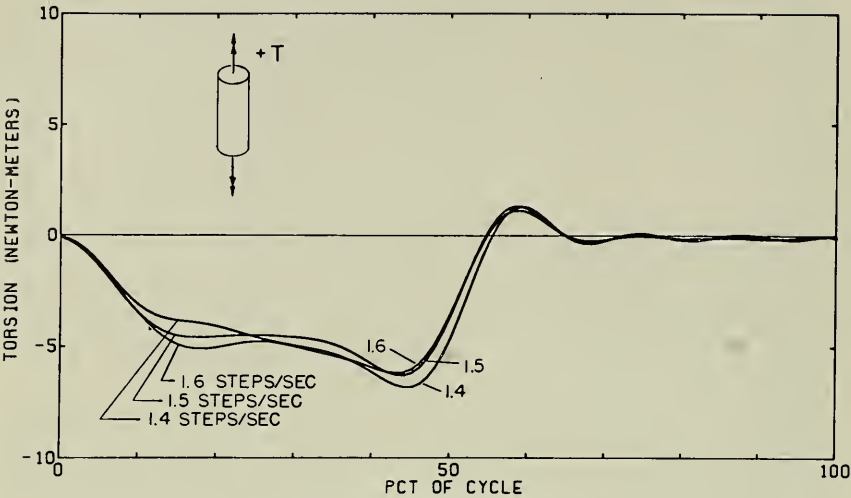
FIGURE 7.—Measured shank torque.
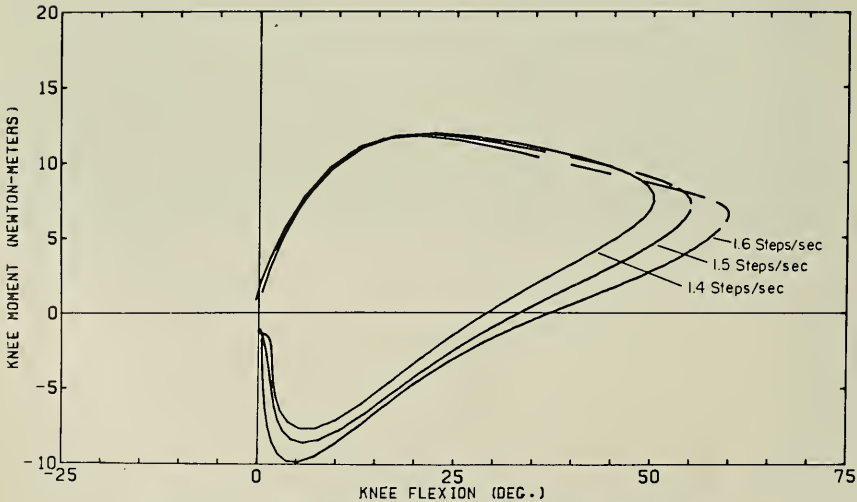
FIGURE 8.—Knee moments and angles during swing phase.

To deal with this alignment problem and still retain the advantages of electrogoniometry, mechanical linkages were devised which permitted the angular position between body segments to be measured without any requirement for precise alignment with anatomic joints. These devices, which now are referred to as Self-Aligning Goniometers, were first used in the three-dimensional motion studies reported in 1970.

The original devices were rather complex and heavy, but were very effective, and efforts have continued to develop simpler and more easily applied devices based on the same concepts. The most recent example is the device shown in Figure 9 which measures flexion angles at both hips and both knees of normal or amputee subjects. Further simplifications are planned for this device, and another device is under design for measuring all three angular components of the total motion between shank and shoe. These efforts are directed toward the development of clinically practical gait evaluation devices.
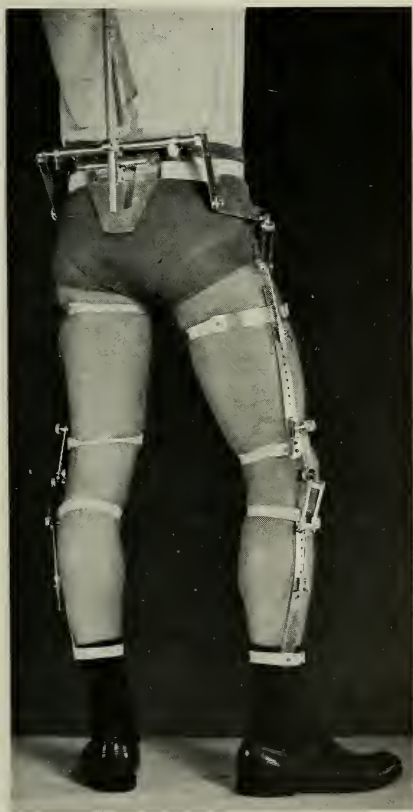
FIGURE 9.—Self-Aligning Goniometers for hip and knee.

5. Data-Control Information

Motion can be defined as a change in position which occurs over a period of time. Consequently, the fundamental variables of motion are time and distance. Locomotion is a specialized type of motion which in humans is accomplished by cyclic sharing of support between the two legs. Any systematic analysis of motion, or of locomotion, necessarily begins with measurements of distance and time. As a result of its cyclic nature, human locomotion is subdivided into basic units of steps and strides. Therefore, measurements of time and distance for each of these cyclic units represent the simplest and most fundamental numerical description of walking which is possible.

Because of the fundamental significance of such measurements in the study of walking, considerable effort has been devoted to the development of reliable techniques for obtaining the measurements and displaying them clearly. The display which has been found to be most satisfactory and useful is a two-dimensional plot of step length versus step frequency. Experience has shown that, for most people, step length and step frequency increase approximately in proportion to one another as walking speed is increased. Furthermore, the same person walking at the same values of step length and step frequency will use the same motion patterns with a surprising degree of repeatability.

These experimental observations have led to the use of the fundamental time and distance measurements as control variables in the collection of kinematic and kinetic data on walking. The variables are always measured, no matter what the primary objective of the experiment may be, and are displayed as shown in Figures 10 and 11. They are not used to control the experiment directly, but to provide a basis for preliminary evaluation and screening of the recorded data. For analysis of a subject's gait over a range of walking speeds, only those data are considered which were recorded at values of step length and step frequency typical for that subject.
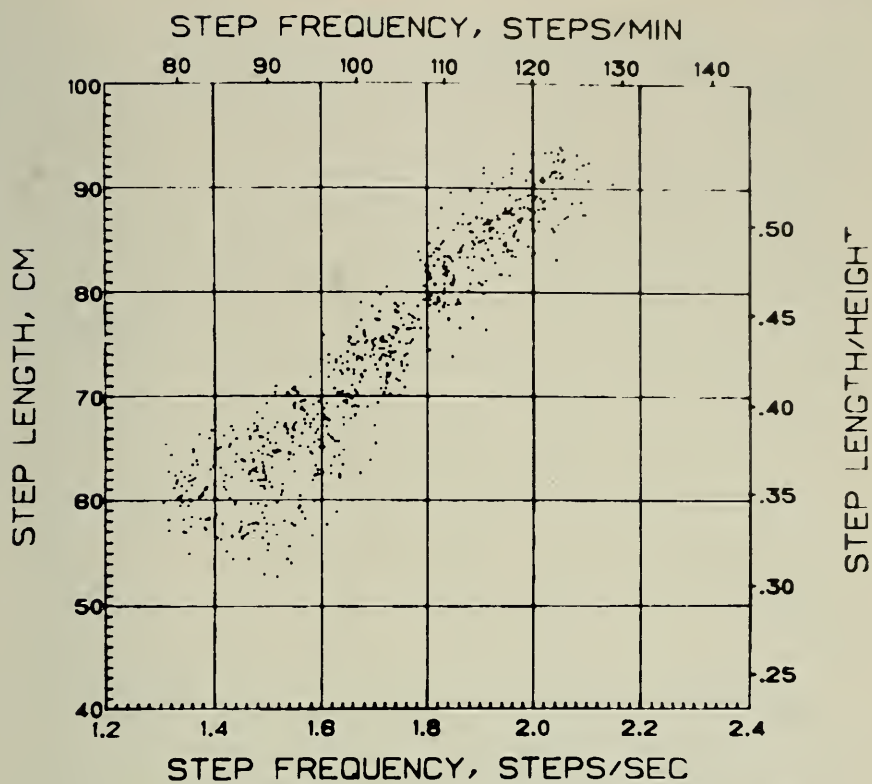
FIGURE 10.—Typical step dimension plot. Each point represents one step.
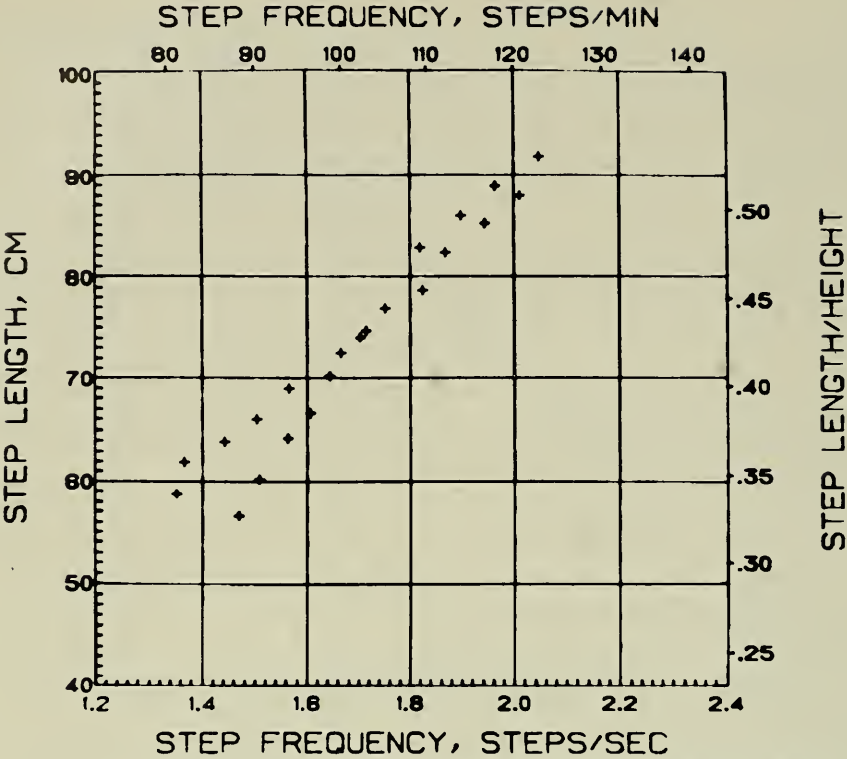
FIGURE 11.—Summary step dimension plot. Each symbol represents an average value for several steps at constant speed.

6. Gait Evaluation

The locomotion laboratory has been developed with the view that documentation of changes in gait is the first step toward improved gait performance evaluation. The first order of priority was instrumentation for the basic time and distance parameters of gait, as described in sections 1 and 2. These data are useful in themselves for gait evaluation, and they are a necessary beginning for any comprehensive description of a particular gait, but they by no means present a complete picture of walking. Many other interrelated variables are involved in walking, including times of stance and swing or of single support and double support, linear and angular motions of the pelvis and trunk in space, and motions of hip, knee, and ankle joints. All of these are combined and correlated to alternately swing the legs forward and continuously support the body against gravity without the impact and jarring which one might expect with such a mode of locomotion.

The next step in developing practical gait evaluation techniques is to select the next most significant variable or variables and provide simple procedures to measure them and display them so that significant relationships are clearly visualized. Practical considerations usually limit the number of related variables to be considered at one time to two; a single graph can easily show relationship between any two variables.

It is not immediately obvious which variables are most significant for purposes of evaluation; only experience will tell for certain. But experience is gained by testing hypotheses, and a strong argument can be offered in support of hip flexion and knee flexion as two very significant variables whose interrelated actions have a great deal to do not only with efficient swinging of the legs forward during swing phase but also with smooth support of the torso during stance phase.

The Self-Aligning Goniometers discussed in section 4 above and shown in Figure 9 provide a practical means for measuring hip and knee flexion angles, and the oscilloscope provides a simple means for displaying the results. Unfortunately, a conventional plot of the two variables against time does not provide the desired clear visualization of relationships between hip and knee flexion. A more suitable display is obtained when the two variables are plotted against each other, with time as a parameter, as shown in Figures 12 and 13. (The still photographs do not properly convey the characteristics of this plot.) It appears without delay on the oscilloscope screen as the subject is walking. Successive cycles are automatically superimposed, clearly conveying an impression of variation from cycle to cycle. Changes in the interaction between hip and knee are characterized by distinct changes in the shape of the closed loop pattern. An oscilloscope camera provides a quick, permanent record which can be placed in the patient's medical records.

ABOVE-KNEE AMPUTEE — SINGLE-AXIS PNEUMATIC KNEE
Height = 182 cm   Weight (with prosthesis) = 91 kg
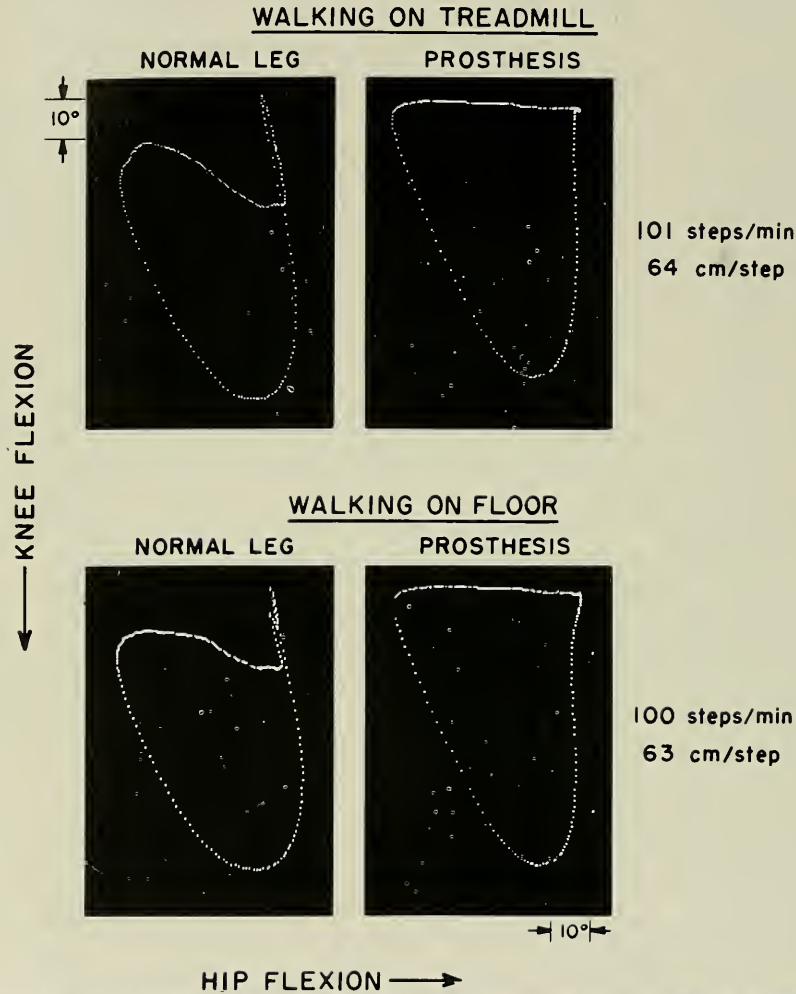
FIGURE 12.—Hip-knee angle diagrams for above-knee amputee wearing single-axis pneumatic knee.

ABOVE-KNEE AMPUTEE — POLYCENTRIC-PNEUMATIC KNEE
Height = 182 cm   Weight (with prosthesis) = 91 kg
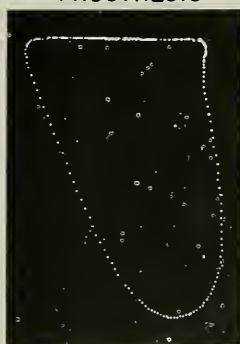
FIGURE 13.—Hip-knee angle diagrams for above-knee amputee wearing Four-Bar Polycentric Pneumatic Knee.

ENGINEERING-DESIGN AND PROTOTYPE TESTING
OF LOWER-LIMB PROSTHETIC AND ORTHOTIC DEVICES

1. UC-BL Four-Bar Polycentric Pneumatic Knee

Ten production-prototype models as manufactured by the Hosmer Corporation have been forwarded to the Veterans Administration Prosthetics Center for further testing. A new spherical socket/knee coupling has been added to the basic knee unit. This adjustable coupling allows ±5 deg. rotation adjustment of the socket relative to the knee in flexion/extension and adduction/abduction plus unlimited axial rotation. An instruction manual has been prepared which includes material on biomechanics of linkage knee mechanisms, the pneumatic swing-phase control, and instructions for installation, alignment, and adjustment of the device for the individual amputee.

Ten units have been reserved for amputee testing in the San Francisco Bay Area. Four units have been fitted to date. One active amputee has worn his UC-BL prosthesis for 1 year without malfunction. Some units fitted in the Bay Area also include the UC-BL shank axial-rotation device.

The cosmetic cover continues to be the major unsolved problem and UC-BL staff members are working with Hosmer Corporation in an effort to produce a satisfactory solution. The present cover provides a temporary solution but will require additional development work, particularly in those cases in which the axial rotation unit is added to the basic knee mechanism.

2. UC-BL Shank Axial-Rotation Device

Amputee testing of the axial-rotation device in the San Francisco Bay Area has been very encouraging. Five units are in daily use with two units having been in service for over 1 year without a mechanical malfunction.

Amputee reaction can be described as enthusiastic on the part of the four above-knee wearers. One below-knee amputee with a short stump has experienced some torsional instability when load is carried on a flexed knee with a PTB prosthesis, but he continues to wear the prosthesis.

3. UC-BL Six-Bar Linkage Knee-Disarticulation Prosthesis

An in-depth study of possible six-bar linkage arrangements has been carried out by graduate students as Master of Science research projects. At present six different arrangements have been shown to be kinematically feasible but only two seem to be practical from a prosthetic standpoint.

The unit designated as Prototype 3 has been redesigned to permit a reduction in width by relocation of the swing-phase control cylinder. The redesign uses the body of the swing-control cylinder as the shank structure. The unit has been modified and fitted to an amputee for testing. The function of the unit continues to be excellent.

4. Tube Couplings for Modular Prostheses

The trend toward modular construction of prosthetic legs has led to increasing use of aluminum tubing for the main structural element of the shank. Tubing provides high strength with light weight and is easily cut to length, so it is well suited for use as the shank module, particularly when used with quick-disconnect foot and knee couplings. The foot coupling is the most critical element of a modular shank structure, because practical cosmetic treatment requires a small cross section at this same level, where maximum bending moments are applied during walking.

Following its introduction with the below-knee adjustable leg, tubing of $1\frac{5}{8}$-in. o.d. and $\frac{1}{16}$-in. wall has been used routinely for pylons in prostheses designed at the Biomechanics Laboratory. The choice of this size originally was dictated by a limitation of readily available stock sizes. There never has been any problem of strength with this tubing, but its large size has caused some complaints from prosthetists who encountered difficulty when cosmetic treatment of small ankles was attempted.

In response to the recent suggestion for an international standard pylon tube size of 35 mm. ($1\frac{3}{8}$ in.), a new foot coupling for this smaller tube was designed. In order to minimize the pylon diameter in the ankle region and to retain as much of the strength of the tube as possible, the coupling fits inside the tube and the tube is not split. Strength tests have shown (see Fig. 14) that the new pylon-foot coupling system of $1\frac{3}{8}$-in. o.d. is actually stronger than the previously used large pylon tube and coupling system of $1\frac{7}{8}$-in. o.d., despite the $\frac{1}{2}$-in. reduction in diameter at the ankle.

EVALUATION AND FURTHER DEVELOPMENT OF NEW DESIGNS FOR BACK BRACES

1. Studies of Spinal Supports

During the past 7 months, the semiflexible body jackets made of laminated polyester resin (4110) with fiber glass reinforcement have been fabricated and tested in four prosthetic-orthotic centers across the country under the auspices of the Committee on Prosthetics Research and Development, National Academy of Sciences—National Research Council. Instructions for fabrication have been prepared and distributed.
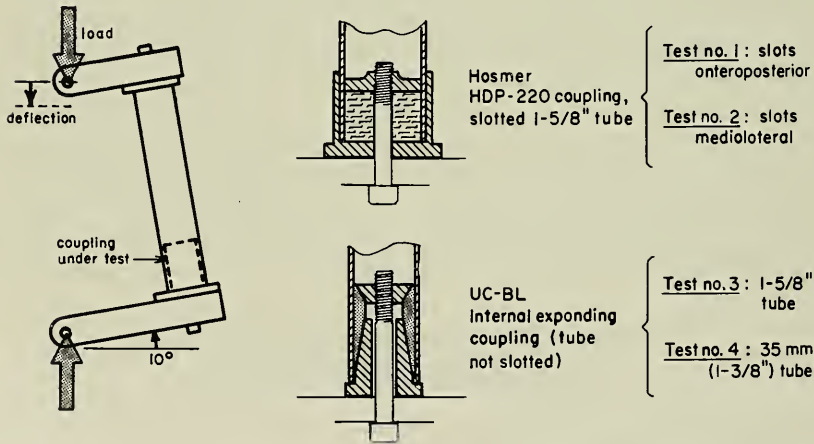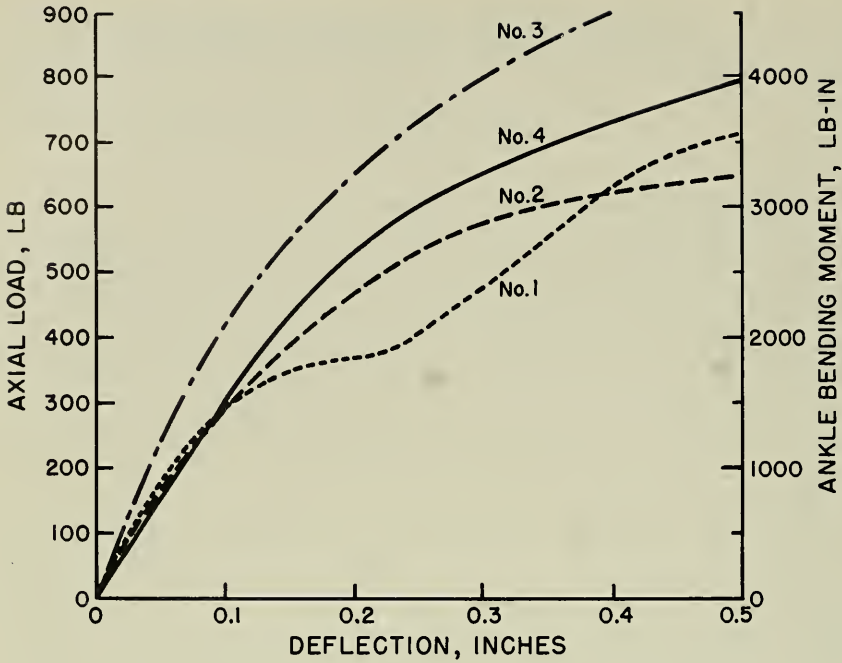
FIGURE 14.—Selected results of laboratory strength tests of modular foot couplings.

Thirty-five patients at the University of California, San Francisco, have worn the device. The results have generally been good. Failures occurred in a few cases, usually because of improper selection of patients, i.e., patients with problems not amenable to improvement by bracing.

A new clinic on problems of low back pain is being set up at UC-SF. Further subjects will be treated with the body jacket, as indicated.

VARIABLE-HEIGHT-POWERED WHEELCHAIR

1. General

The interim version of the UC-BL wheelchair was completed to a point at which it was tried by a quadriplegic and a motion picture of activities of daily living was made. By "interim" we mean that this version will not climb curbs, but will fit into an automobile later on. Much enthusiasm was expressed by the quadriplegic after one day of use, in spite of his initial reservations about the need for any of the unique extra features of this wheelchair.[a]

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[a] See D. M. Cunningham's article "Variable-Height-Powered Wheelchair for the Quadriplegic Driver," appearing elsewhere in this issue of the Bulletin.

CLINICAL GAIT ANALYZER

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ABSTRACT

This report describes the development of a clinical gait analyzer designed to measure the patient's velocity and single limb support time. The unit can be used in any environment that has at least a 10 m. walkway.

The memory unit has been designed and a prototype is ready for testing. A preliminary design of the calculator-display unit has been completed. Gait tests with 33 normal subjects were conducted to establish a normal single limb support time (single stance time) velocity curve.

DEVELOPMENT OF A GAIT ANALYZER

Measurement of gait provides an objective correlation between functional capacity and physical impairment. In amputees the significance in walking ability of the level of amputation and a vascular etiology for the impairment has been clearly demonstrated. The technique also has been used to define the functional level of patients at the time of their total hip replacement surgery and their postoperative gains.

To obtain this information the patient is outfitted with a pair of insole foot switches and then asked to walk along measured walkway while a timed recording is made. Both customary and fast gait are recorded.

Each insole contains a cluster of contact closing switches in the areas of the heel, first and fifth metatarsal heads, and the great toe. Their output is electronically coded to indicate which areas of the foot are contacting the ground. The normal sequence (heel, heel and fifth, flat foot, and forefoot) is displayed as a staircase. Unusual support patterns (fifth or first only or heel and first) are identified as half steps. A 16 m. walkway provides a starting and stopping area at each end of the middle 6 m. segment that is defined by photoelectric cells. This middle interval is used for data analysis. All data are transmitted via telemetry to the recording system. The output is a printed record of the two foot-switch patterns and the photoelectric signals designating the 6 m. area.

These records are interpreted by manual measurement of the stance and swing intervals and their subdivisions. With appropriate calculation one can identify velocity, cadence, stride length, gait cycle duration, single stance, double stance, swing-stance ratio, and the pattern of foot support. Correlation of these data with the clinical course of patients with total hip joint replacement has indicated some factors are more representative than others.

Velocity is the product of cadence and stride length. With only infrequent exception all three factors have been found to change in the same direction as the patient's status changes. So velocity can be considered representative of this group of data and indicative of his general mobility.

Double stance time, while denoting a period of weight exchange, fails to identify the relative contribution of the two limbs. In contrast, single stance is an interval of total weight acceptance and hence a clinically important period. However, its absolute duration is not meaningful as the very slow walker who seemingly only briefly stands on his limb may use as much time as a speedier person with a proportionally much longer stance interval. When single stance time is correlated with the person's velocity, it has clinical significance.

Swing-stance ratio also was found not to be representative of pathology. In patients with unilateral hip disease, that limb maintains a virtually normal ratio while the sound side may alter its swing and stance times drastically to accommodate for contralateral impairment. Patients having bilateral disease may display normal ratios even though all intervals are prolonged. For these reasons single stance time as a percent of normal for the measured velocity has been selected as a clinical index of the limb's weight-bearing tolerance.

The limitation to adoption of this system in the clinics has been the chore of making the manual measurements and calculations. This act is too foreign to the routine working of the clinical staff. Hence the current objective is to develop a gait calculator. A gait analyzer (clinical gait analyzer) is being designed to automatically identify the patient's velocity and percent of normal single stance time.

The clinical gait analyzer will consist of a memory unit, which stores the data obtained from the patient, and a calculator display unit, which calculates the patient's velocity and percent of single stance time, displaying the results.

The memory unit will be a small electronic package worn on the belt of the patient (Fig. 1). Data will be fed into the memory unit from foot switches worn by the patient and from a switch operated by the person running the test. The operator's switch will identify the beginning and end of a measured walkway for purposes of determining the patient's average velocity.

CLINICAL GAIT
ANALYZER

(MEMORY UNIT)
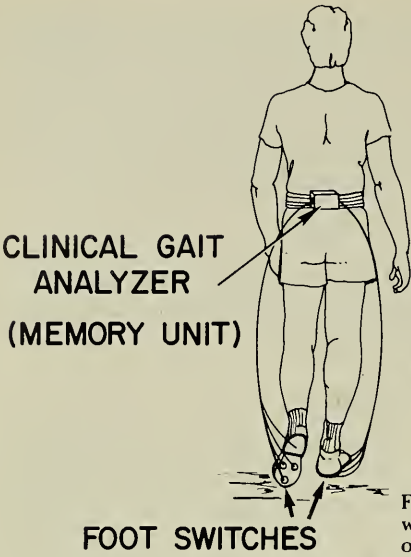
FOOT SWITCHES

FIGURE 1.—Artist's concept of patient walking with clinical gait analyzer (memory unit).
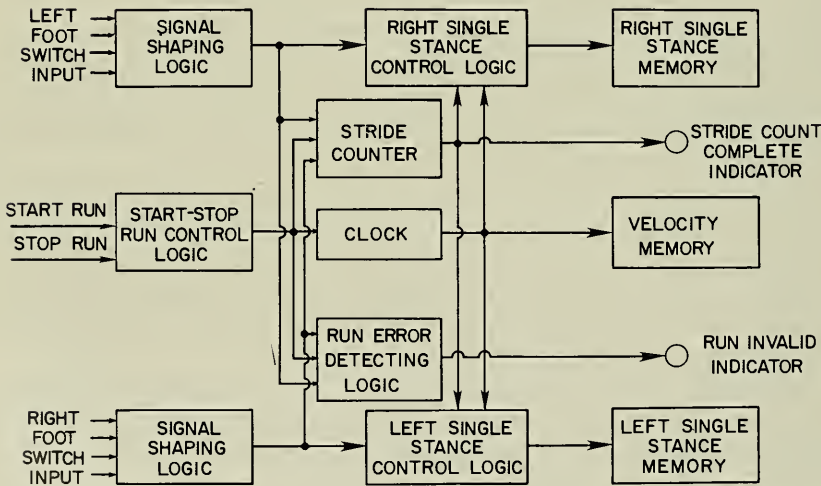
FIGURE 2.—Block diagram of clinical gait analyzer (memory unit).

The left and right foot switch data will be obtained by detecting the absence of any foot-switch closures which indicates the limb is in swing phase. This gives a measure of single stance time since swing equals contralateral single stance. These data will be fed into signal processing logic circuits (Fig. 2) which delay the data 100 ms. to eliminate unwanted short duration (less than 100 ms.) artifact signals. These might occur as a result of a sticking foot switch or a tow scuff during swing phase. The processed foot-switch signals will be fed simultaneously into three logic circuits, a stride counter, a run error detector, and a single stance control. The single stance control logic circuits will restrict the recordings to those obtained from the first three strides that follow the "start of run" signal.

The stride counter will count the strides and control the single stance control logic. If three strides are completed prior to the end of the run, the stride count complete indicator will come on. If this indicator does not come on, the person conducting the test knows the single stance data is invalid due to an insufficient number of strides being completed during the test.

The run error detecting logic will determine whether a proper step sequence has occurred. Specifically, left initial stance must follow right terminal stance and conversely, right initial stance must follow left terminal stance. If this sequence does not occur, the run is invalid due to an improper step sequence, and an indicator will come on. Situations which would cause this condition are hopping, resting on the swing side during swing, a long toe scuff during swing, a broken foot-switch wire, etc.

The start-stop run control logic will allow data to be recorded only during the time the patient is walking through the measured walkway. The clock will generate pulses at a fixed repetition rate. These pulses will be counted and stored in the memories providing a measure of the single stance times and the velocity.

The calculator display unit (Fig. 3) will have a memory into which are stored the single stance times for normals as a function of velocity. When the memory unit is plugged into the calculator display unit and the velocity button is pushed, the patient's velocity will be fed into the calculator and a normal single stance time will be selected for that velocity from the stored data. The patient's average single stance time for three strides will be calculated and the ratio of this value to the normal single stance time will be computed and displayed (as a percentage) on the digital display.
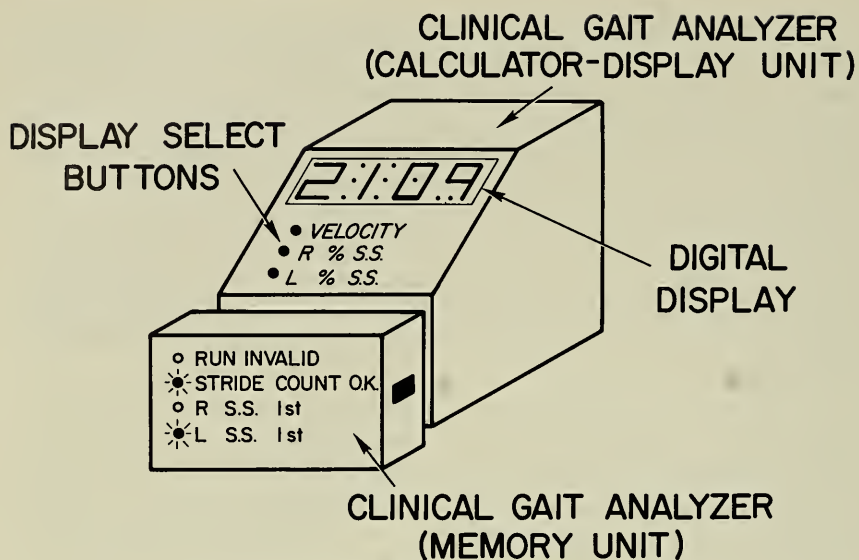
FIGURE 3.—Artist's concept of clinical gait analyzer.

IN VIVO LOADING ON KNEE JOINT REPLACEMENT

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The Biomechanics Laboratory of Case Western Reserve University has had considerable experience in the techniques of radio telemetry of *in vivo* load data. Our work on the total knee replacement has been greatly influenced by our previous experience with instrumented hip nails. For several years we have been conducting a study of *in vivo* loads imposed on hip nails used to treat various disorders of the proximal femur. Nails containing telemetry instrumentation have been inserted in five patients. These patients have been monitored for periods of 6 months. This is sufficient time to follow the course of recovery from the various operative procedures. During this 6-month period, the devices were monitored while the patients were performing various activities necessary for daily living. In addition, the nails were checked while the nursing staff cared for the patients. Finally, when the patients were ambulatory, nail loads were noted during all critical phases of early ambulation, and periodically during the later recovery period. Particular care was taken to record early transient activity such as climbing out of bed for the first time, getting into a wheelchair for the first time, or using a walker.

The instrumented hip nail was designed and constructed at Case Western Reserve University. The nail is a two-piece design (Fig. 1). The main body, made of 316L surgical grade stainless steel, contains all structural elements necessary to provide the strength and rigidity needed to perform its biomechanical function. In addition, the main body contains two cavities, one of which accepts the strain gage instrumentation and batteries, while the other houses the electronic circuits. The second piece of the nail is a cover plate which is used to mechanically seal all electronic components from the external environment.
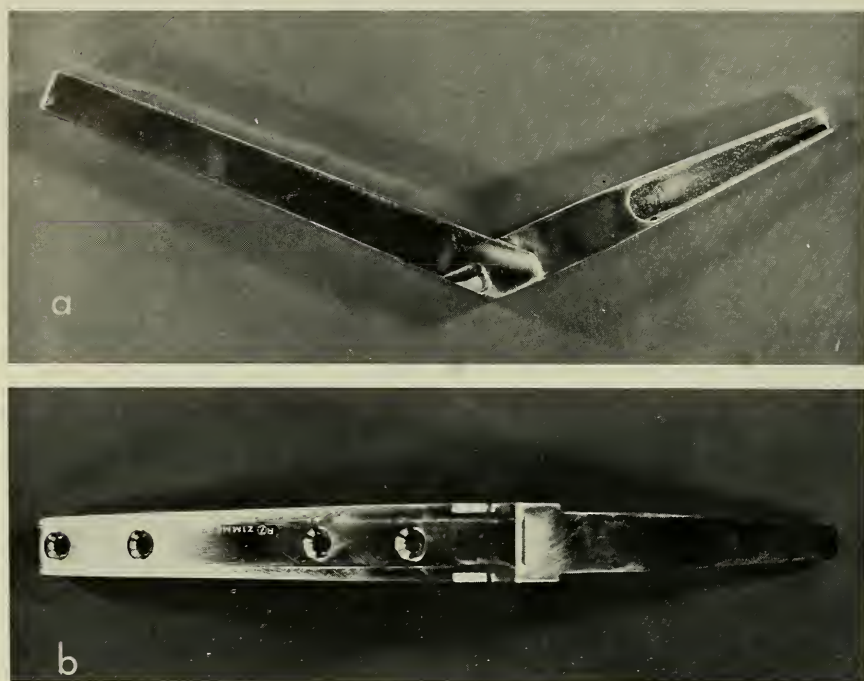
FIGURE 1.—Instrumented hip nail, a. anterior view and b. lateral view.

In addition to the primary mechanical seal provided by the cover plate, two secondary sealing systems are utilized. Under the primary mechanical seal a coat of biological grade silicone rubber is used to separate all the metal surfaces from the third seal which is a low chloride epoxy. Thus, all electronic components are encased in epoxy resin which is in turn covered with medical grade silastic which is in itself completely surrounded by the 316L stainless steel. There are no wires or other electronic devices extending from the nail. Only tissue interfaces the stainless steel. Several of the nails utilized in patient studies have been recovered after periods of implantation from 5 to 9 months. These nails were sectioned and examined for possible fluid contamination of the electronic compartment. No evidence of fluid contamination was found beyond the primary seal.

The electronic circuits consist of two channels of signal generators whose output is a sinusoidal wave in the audio frequency (3,000 and 10,000 Hz). These a.c. signals are modulated in each of the strain gage circuits. The modulated signals are then mixed and sent into an FM transmitter. The AM-FM signals are received by an ordinary FM broadcast receiver where the FM signals are demodulated. The AM signals are

then separated by narrow band pass filters, and the individual signals are amplitude demodulated.

The designs of total knee joint replacements are now well into their third generation. The earliest of these designs are typified by the fixed hinge type of device which required two long stems or skeletal attachments into the femur and tibia. The second generation of devices utilized a sliding joint concept in which one of the halves of the joint replacement was strictly a metal component while the contacting surface was manufactured of high density polyethylene. Third generation designs are now being evaluated and include various combinations of the previously mentioned two design concepts.

Several different design techniques have been utilized in constructing the sliding joint type of total knee prosthesis. Some of these designs have incorporated separate condylar replacement components for the distal femoral portion. The type of design which we have chosen to instrument is of this duo-condylar nature. The reason for this choice is that instrumentation of the type of device which has both lateral and medial condyles cast in the same integral section would allow only the total load borne by both condyles to be monitored. It is possible that some information could be obtained as to loading distribution. Instrumentation of separate condyles, however, allows us to monitor separately the load in each of the condyles and this would give rise to a more accurate and useful measurement of the actual loads that are imposed on each condyle of the knee joint replacement. The loads recorded for the separate condylar prosthesis would of course be entirely applicable in designing a prosthetic device with attached femoral condyles. There is no reason to suspect that the load pattern would be different in response to the design of the prosthesis itself.

Each of the femoral condyle replacements has been constructed according to the design shown in Figure 2. The actual contact surfaces of these prostheses are very similar in nature to those of the available commercial types. The basic difference between the two structures lies in the fact that the body of the prosthesis is instrumented with strain gage telemetry devices. Mechanical construction of the devices is such that all loads must pass through the instrumented central portion before the load is ultimately distributed to the methylmethacrylate and then to the bony portion of the femur. Our instrumentation allows up to five channels of loading information to be monitored simultaneously. These five channels will allow the determination of surface loads on the prosthesis and will allow the investigation of some of the frictional phenomena associated with artificial joint motion. The design of the prosthesis is such that standard high density polyethylene tibial components may be used in conjunction with the instrumented femoral portion. At the present time we have a completely manufactured and

instrumented prototype which was built of aluminum to allow evaluation of the mechanical design as well as the telemetry components (Fig. 3). This prototype prosthesis performed satisfactorily in all respects. We therefore started production on 12 unicondylar knee prostheses at Case Western Reserve University.
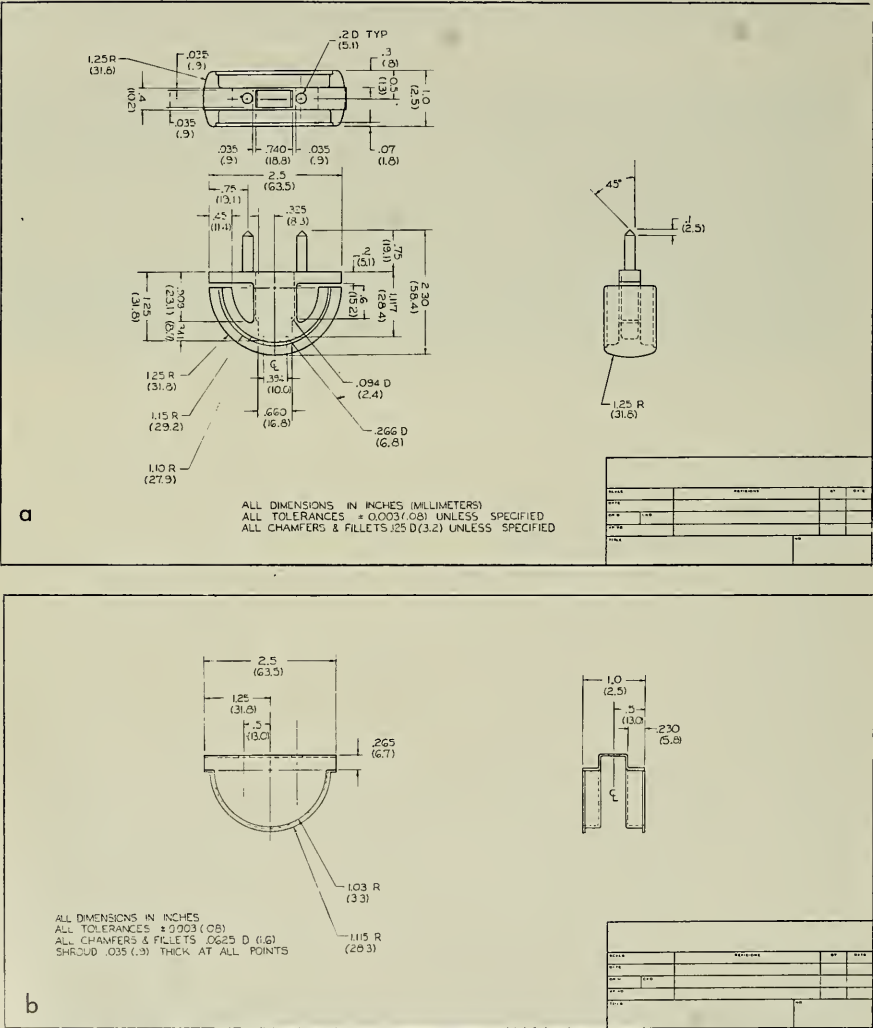
FIGURE 2.—Design of femoral condyle replacement, a. inner portion and b. shroud.
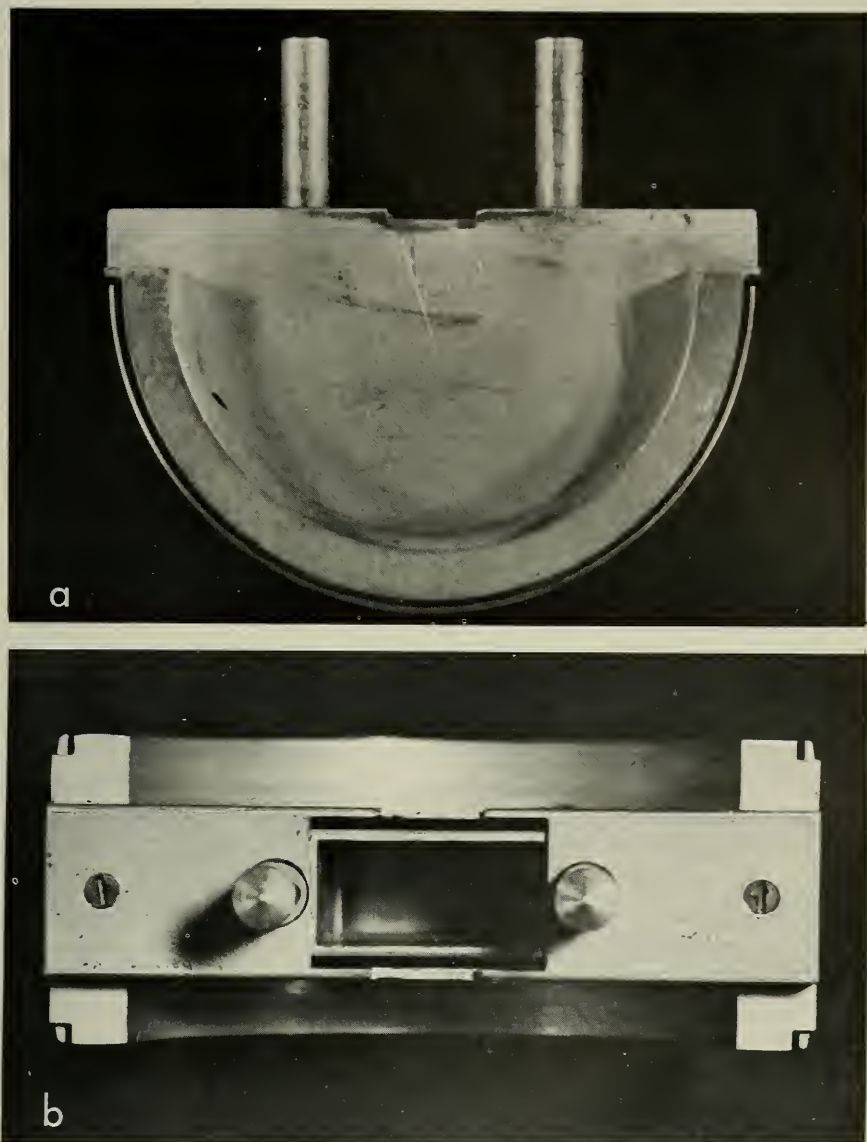
FIGURE 3.—Prototype instrumented knee prosthesis, a. side view and b. top view showing instrumentation compartment.

The electronic circuitry is shown in circuit diagram form (Fig. 4). The circuit consists of five parallel signal generators each operating at a different audio frequency. The outputs of these five signal generators power five independent strain gage bridges each with two active arms and two dummy arms. The audio frequency sine wave is amplitude

modulated as it passes through each bridge. The lowest frequency chosen will be approximately 3,500 Hz. This allows adequate signal resolution down to approximately 300 Hz. All other channels will have resolution capabilities of above 500 Hz. This is deemed more than sufficient for the type of data that are to be recorded. The output signal from the individual bridges are then summed in an operational amplifier. This summed signal is then fed through a transformer circuit into an FM transmitter. The transmitter, a model K-6, is supplied by the Biomechanics Laboratory at Case Western Reserve University, Wen-Hsiung Ko, Ph.D., Director. By varying the geometry of the coil, in the circuitry of the transmitter, an appropriate FM frequency can be chosen. A single battery pack is used to power all electronic instrumentation. The circuit may be turned on and off remotely by means of a magnetically actuated reed switch. As outlined on the diagram in Figure 4, the circuitry consists physically of three flat packs and their associated electronic components, one battery pack, one magnetic reed switch, and one transformer. Three signal generators and all necessary electronic components are assembled about one flat pack while the remaining two signal generators and the summing amplifiers are assembled on a separate flat pack. The K-6 FM transmitter and the necessary power supply and input circuitry are assembled onto a third flat pack. The actual configuration will incorporate eight batteries. Since there is more than the necessary minimum internal volume in currently produced femoral prostheses, no packing problems were encountered within the prototype using the necessary batteries. The necessary monitoring instrumentation has been designed and assembled in the Biomechanics Laboratory, so that at the present time we are ready to monitor the first patient who will receive the instrumented prosthesis.

In order to monitor the telemeterized signal from the total knee prosthesis, a single commercial FM receiver is employed. The FM transmitter in the prosthesis is tuned to operate approximately at the 89m Hz frequency range. The FM demodulated signal from the tuner is fed directly into a two-channel audio tape recorder. It must be remembered that the demodulated FM signal is within the audio range. The audio tape recorder is used only in studying the patient in the operating room and in the immediate postsurgical period. After a period of approximately 3 or 4 days, the patient is capable of being brought into the Gait Laboratory and data storage is then accomplished using a standard 14-channel instrumentation tape recorder. This is the same tape recorder that is currently employed to store the output signals from the force plate and EMG receivers, and comprises an integral portion of the instrumentation of the Gait Laboratory.

Both the FM receiver and the tape system are calibrated with a gain factor prior to each run. This is accomplished by monitoring an AM-FM
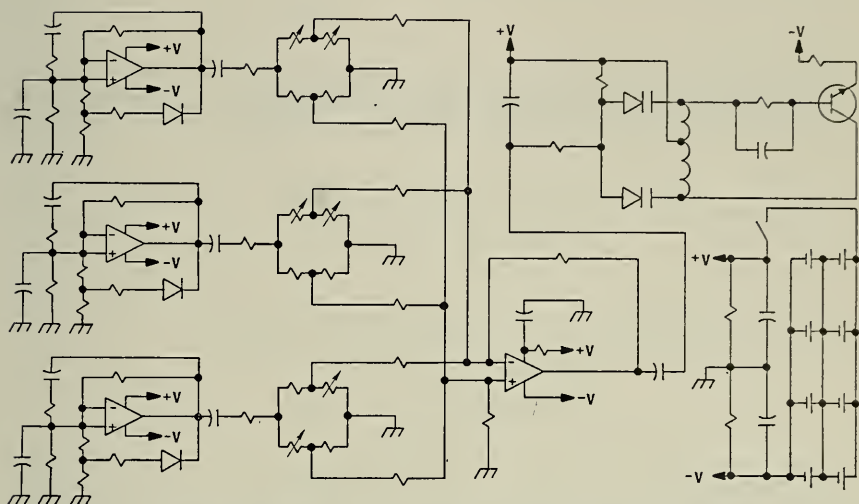
THREE CHANNEL AM/FM IMPLANTABLE TELEMETRY CIRCUIT

FIGURE 4.—Three channel AM-FM implantable telemetry circuit.

signal with the AM wave carrying a modulated square wave signal of known amplitude. The gain of the system is also adjusted by allowing the patient to remain at rest and by comparing the relative amplitudes with the signals of all channels. In each experimental procedure there is one channel when the relaxed patient is in a position which is most likely to be unloaded. For example, with the knee in 90 deg. of flexion and the thigh portion supported just behind the knee, the joint would not be subjected to an axial load. In each case, this signal gives a reference level which allows the internal calibration of the amplitude modulation circuit.

With the amplitudinal modulated signal stored on tape, demodulation may be accomplished at a later convenient time or it may be accomplished simultaneously with testing for immediate evaluation of testing procedures. In either case the mixed AM signals from the five channels are fed through a bank of five band pass filters. This effectively separates the frequencies which are then amplitude demodulated. These signals may now be recorded on a strip chart recorder.

A SEARCH FOR BETTER LIMBS: PROSTHETICS RESEARCH AT NORTHWESTERN UNIVERSITY

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HISTORICAL PERSPECTIVE

The Rehabilitation Institute of Chicago established the first private Amputee Clinic in the Chicago area in 1954. In 1958, with financing by the Veterans Administration, a prosthetics research facility was established in the physical facilities of the Rehabilitation Institute by the Department of Orthopaedics, Northwestern University Medical School. From its inception the activities of the Prosthetics Research Laboratory were clinically oriented and dedicated to improving the lot of the amputee, whether he had upper-limb or lower-limb loss. Because of interested clinicians' attendance at the Veterans Administration Regional Amputee Clinic, liaison between the problem veteran amputee and the Prosthetics Research Laboratory was early established.

Early on, the laboratory directed its attention to the area of greatest complaints by amputees, namely the socket-limb interface, and some of the earliest work of the laboratory involved improving techniques for casting and socket fabrication. Suspension casting was one of the techniques which was developed and tested. Many other experimental techniques resulted in definitive procedures that have stood the test of time. Further attention to the same problem resulted in a considerable effort to provide flexible, fluid-filled sockets.

It was early noted also that prosthetic joints required attention, particularly in the above-knee amputee who required not only stability in stance phase, but control of extension and flexion at the knee. The Northwestern variable-cadence knee was one of the early attempts at providing this type of knee function. Due to the large geriatric population of the Rehabilitation Amputee Clinic, a polycentric knee providing improved stance stability was also designed. Improved hip joint alignment control was possible with the Northwestern modification of the hip joint used in the Canadian hip-disarticulation and hemipelvectomy

prosthesis. Several new techniques were developed in fabrication of hip-disarticulation sockets and in the casting of amputees with this difficult prosthetic problem.

It was observed, that the prostheses for upper-limb amputees were also in need of improvement, even though considerable advances had been made since World War II. It was noted that, as one approached the shoulder-disarticulation level, prosthetic replacement was far from satisfactory, in most cases producing only frustration on attempted use. This was particularly acute in the bilateral short above-elbow amputee or the bilateral shoulder-disarticulation amputee. The Michigan feeding arm used by child amputees of the Michigan Crippled Children's Amputee Clinic was developed for this problem. This arm employed electric power and a kinematic coupling technique, coupling elbow and wrist movements, to produce a satisfactory eating function. Adaption of this arm for use by adults was not considered feasible.

The Northwestern ring harness was one of several innovations in upper-limb harnessing. Other items developed for upper-limb problems were a center control hook and a variable lift-tab assembly. Early attempts at providing external power for the upper-limb prosthesis were in the realm of powered assistive devices. These mechanisms were investigated, designed, and subsequently used by several amputees. By 1970 the concept of muscle electricity to provide prosthetic control was also becoming important, and a considerable study was undertaken to improve myoelectric systems, to increase reliability, improve function, and develop simple fitting methods.

Through the years the Laboratory has come to realize the value of close cooperation between the amputee, physician, prosthetist, therapist, and engineer. We feel that this team approach can most effectively attack the problems of prosthetics research and development. Modulation of designs and techniques through interaction of members of this group can keep the work practical and goal-oriented.

RECENT OBJECTIVES

Laboratory involvement in upper-limb work during recent years (since 1970) has had a tendency to be self-perpetuating. This apparently has occurred because even minimal success has resulted in the referral to the Laboratory of a number of amputees having special needs or difficult prosthetic problems which correspond vaguely to the work already going on. Consequently, there has been a pyramiding of activity in the upper-limb area. What follows summarizes some of this recent activity. Some of these developments span a period of 2 to 3 years and are considered "medium-range" projects. Other projects are "short range" in nature and may only involve the solution of one problem for one

person. The "short-range" findings are usually not radical departures from existing principles and may not require long development and evaluation programs. Nonetheless, they may be very important in the prosthetic field. Projects which appear to require long gestation periods (5-10 years) are generally investigated outside regular Laboratory activities through interested graduate students of the Technological Institute at Northwestern University. We feel that both long- and short-range research and development are necessary in limb prosthetics.

PRESENT OBJECTIVES

Present objectives of the Northwestern University Prosthetics Research Laboratory are basically as follows:

1. *Develop subconscious control:* In subconscious control the subject controls his assistive device naturally and without consciously thinking about it.

2. *Develop self-suspending and comfortable devices:* Harness and straps are frequently uncomfortable and unsightly and do not provide optimal interface arrangements with the body.

3. *Develop self-contained and cosmetic devices:* Wearers of assistive devices prefer them to be self-contained and simple as well as pleasing in appearance.

4. *Develop high performance and reliable mechanisms:* Mechanisms need to be light, noncumbersome, strong, reliable, and responsive.

5. *Develop rudimentary esthetic qualities in assistive devices:* The disabled person should have a sense of the mechanism as an extension of himself and not as a separate piece of equipment.

6. *Improve existing prosthetic-orthotic components and techniques:* Many disabled people will never use newly developed systems. Improvement of systems which are already well-accepted is important.

Subconscious Control

We have tried to use myoelectric control methods as one approach to subconscious control. One interesting result of our studies is that prehension seems to be the function which is most readily adapted to subconscious control through the use of myoelectricity. This seems obvious with the wrist-disarticulation and below-elbow amputee where finger extensor muscles are used to open the hand and finger flexors to close the hand. It may not be obvious that muscles above the elbow joint or above the glenohumeral joint should also be related to prehension. This may be explained by considering what happens when a person grips an object strongly. Muscles of the arm and shoulder all come into play during strong prehension. It is not surprising then when a shoulder-disarticulation amputee reports that contraction of his pec-

toralis major on the amputated side gives him the impression of closing his hand.

We have made use of the contraction of flexor muscles of the forearm, arm, or shoulder areas and their natural relationship with prehension. Therefore, finger flexors and wrist flexor muscle groups are used effectively for subconscious control of prehension by the below-elbow amputees. A typical fitting is shown in Figure 1.

The above-elbow amputee shown in Figure 2 illustrates how the biceps may be used to control prehension. The triceps open the hand. The elbow is controlled by body-power through glenohumeral flexion. We have found this to be a desirable type of fitting for the above-elbow amputee. Other aspects of this prosthesis which should be noted are the open-shoulder construction and the harness (discussed in detail later).

The shoulder-disarticulation amputee shown in Figure 3 uses the pectoralis major to close his artificial hand and the trapezius to open it. Note the use of endoskeletal construction and of the well-fitted minimal-area socket. Endoskeletal construction can be of great benefit to the high-level amputee through the reduction of prosthesis weight.

Myoelectric control can be used effectively at several levels of amputation to develop subconscious control of prehension. The development of myoelectric hand components is therefore proving to be useful for a wide class of upper-limb problems and is not limited to below-elbow cases. It has its greatest advantage when it can be coupled with self-containment and self-suspension as shown in Figure 1.

FIGURE 1.—Below-elbow amputee wearing a prosthesis with myoelectric control of prehension from the forearm, self-containment, self-suspension (N.U. supracondylar socket), and good cosmesis.
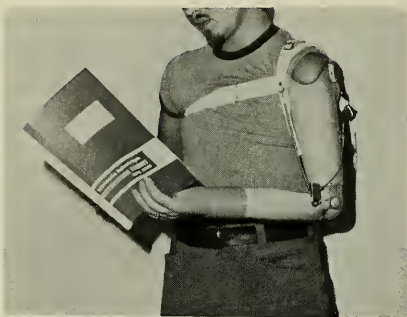
FIGURE 2.—Above-elbow amputee using myoelectric control of prehension from the arm, body-powered elbow, open-shoulder socket, and a thoracic suspension and control harness.
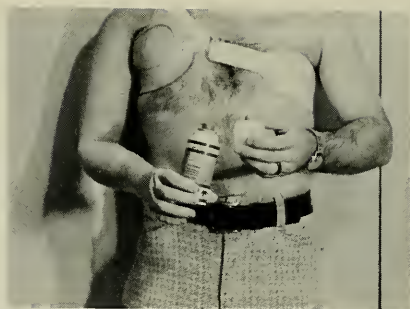
FIGURE 3.—Shoulder-disarticulation amputee using myoelectric control of prehension from the shoulder, endoskeletal construction, chest strap, and minimal-area socket.

Self-Contained And Self-Suspended Devices

A primary continuing goal of the Laboratory is the development of self-suspension techniques for upper-limb amputation problems. Self-containment is a companion of self-suspension and they should occur together, where possible. We have discussed this in earlier papers (1, 2). The Northwestern University approach to supracondylar suspension h; : also been presented (3). We feel that atmospheric-pressure suspension will soon be more widely used for upper-limb prosthesis support. Preliminary results with this type of suspension at the wrist-disarticulation and above-elbow levels have been successful, and it appears that sockets which are a combination of hard and flexible material may have significance in this application. A self-suspension socket and prosthesis are shown in Figure 4 as applied to an above-elbow prosthesis of the cosmetic type. This socket has been described in progress reports of our laboratory (4).

FIGURE 4.—Above-elbow amputee demonstrates a self-suspending socket which employs atmospheric suspension of a cosmetic prosthesis.

Improvement Of Existing Prosthetic Approaches

We know the so-called conventional upper-limb prostheses of the body-powered variety remain popular and in many cases are the most desirable fittings. These systems came into widespread use during the 1950's and have not been substantially changed since then. This attests to their suitability and to their being somewhat the end product of an evolutionary development. Many of today's amputees will continue to use these effectively for the remainder of their lives. We have, therefore, investigated some possible improvements in these basic systems.

1. Harness for the Above-Elbow Amputee

Figure 5 shows a thoracic-suspension and control harness which is being developed. This harnessing scheme, as shown, harnesses glenohumeral flexion. It is simple and affords the amputee greater comfort and good mechanical advantage when compared with the more conventional "figure-of-eight" harness. The chest strap is more comfortable than an axillary loop. The harness is easy to don and doff. Figure 6 shows the posterior view of this harness arrangement as worn by an above-elbow amputee. Figure 2 shows the anterior aspect.

1. Anterior Attachment Strap
2. Thoracic Suspension Strap
3. Anterior Suspension Strap
4. Lateral Suspension Strap
5. Elbow Lock Control Strap
6. Posterior Control Strap
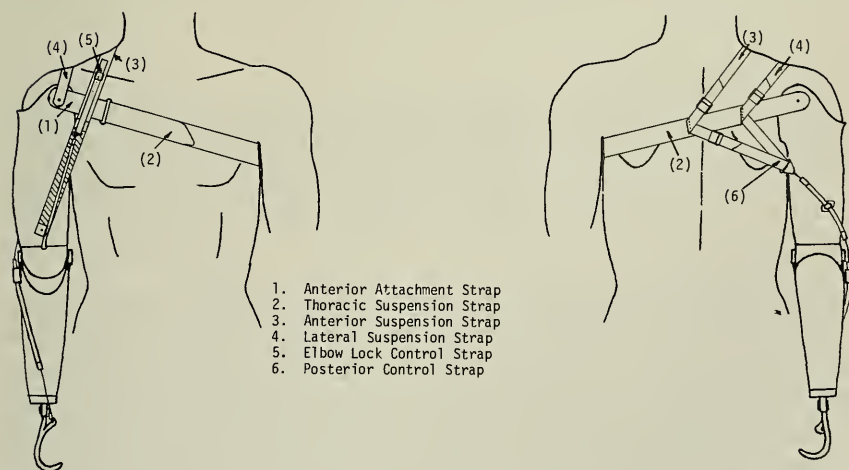
FIGURE 5.—Diagram showing harnessing of glenohumeral flexions for above-elbow, body-powered prosthesis.

FIGURE 6.—Above-elbow amputee using the thoracic-suspension and control harness.

Rotational stability is improved, compared with the "figure-of-eight" harness, in the horizontal plane because of the anterior and posterior attachment of the thoracic-suspension strap. Biomechanical efficiency is improved because the posterior control strap is kept over the inferior aspect of the scapula. The "figure-of-eight" harness may tend to migrate superiorly on an amputee's back during glenohumeral flexion. This results in a loss of power and excursion.

The harness described may be modified for harnessing biscapular abduction. A section of elastic material is inserted in the thoracic suspension strap at the posterior attachment. The medial attachment of the posterior control strap is moved to a point over the scapula on the sound side. This improves the biomechanical efficiency and allows the amputee to utilize both glenohumeral flexion and biscapular abduction for activation of the prosthesis. This is necessary for amputees who have weak glenohumeral flexion.

2. Lift-Lock Mechanism

This work illustrates an attempt to improve function of the dual-cable control system which is so widely used by above-elbow amputees in the United States. They very often use voluntary-opening terminal devices with the result that their ability to lift heavy objects through forearm flexion is limited by opening of the terminal device and not by their own force limitations.

In principle the device functions as illustrated in Figure 7. The control cable passes around a pulley mechanism located where the lift-tab is normally situated. The cable is fixed to this pulley. The pulley is mechanically locked against rotation through a cable attached to the locking bar of the E400 (Hosmer) elbow. When the locking bar is pulled up to disengage the elbow, it pulls a cable which engages a pawl, locking the lift-lock pulley. Cable forces now may be used to lift the forearm, but these forces are not transmitted to the terminal device. Therefore, heavy

objects may be lifted through elbow flexion without being dropped by the terminal device. When the elbow is locked, the locking bar descends and permits the spring-loaded pawl on the lift-lock to disengage. In this condition the pulley is free to rotate, and cable forces are transmitted directly to the terminal device. The unit is shown being worn by an amputee in Figure 8.
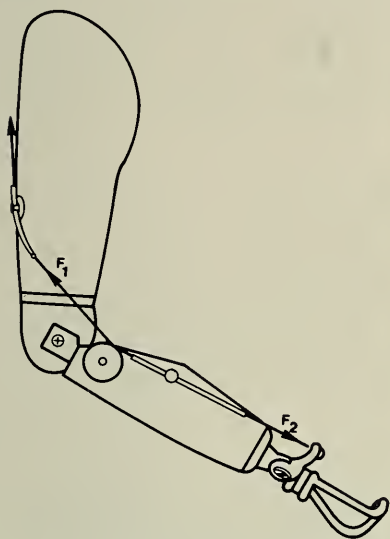
FIGURE 7.—Drawing of above-elbow prosthesis showing the pathway of the cable around the pulley of the lift-lock mechanism.

FIGURE 8.—Lateral view of the lift-lock mechanism as applied to the prosthesis of an above-elbow amputee.

The lift-lock also tends to increase cable efficiency. The cable takes essentially the same bending radius at all elbow flexion angles. With the conventional lift-tab the bending radius is substantially reduced as the elbow flexes. Hence efficiency is reduced.

3. Glenohumeral Joint

We have developed a passive glenohumeral joint which solves some of the problems we had experienced with joints at this level. These problems were mainly lack of sufficient holding torque and variation of this holding torque during usage. We call the joint an "orthogonal cylinder glenohumeral joint" since its principle of operation is based upon cylinders which rotate on mutually orthogonal axes. This principle is widely used with tripod heads for cameras and is of rugged, reliable, and inexpensive construction. It permits passive flexion-extension and ab-

duction of the humeral component. It is easily adjustable, will maintain its resistance over a long time interval, and can be set to resist high torque. This is necessary for holding a hunting firearm or other object of considerable weight. Furthermore, it exhibits minimal "stick-slip" characteristics. It is shown in Figure 9.
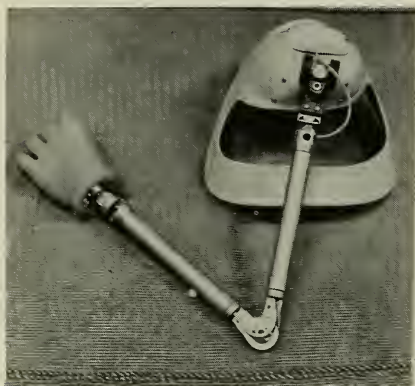
FIGURE 9.—View of glenohumeral joint as applied to a shoulder-disarticulation prosthesis of endoskeletal construction.

Despite physical bulk this unit may be used for shoulder-disarticulation cases, as well as interscapulothoracic cases. For shoulder-disarticulation fittings it needs to be mounted below the acromion to achieve good cosmesis. The joint is now commercially available through the Pope Brace Company.

High Performance and Reliable Mechanisms

1. *Myo-pulse modulation*

In 1972 we disclosed a different approach to myoelectric control called "myo-pulse modulation" (5). This technique is used in the commercial VA/NU hand, and we are still involved in the improvement of the hardware which uses this processing scheme. This approach has the following three distinct advantages over previous myoelectric control circuits:

1. Instantaneous output response to myoelectric input.
2. Exceptionally good control over a wide range of output velocities or forces.
3. Simplicity of design.

In myo-pulse modulation the processing scheme consists only of amplification in conjunction with a small threshold. Positive pulses of the myoelectric signal e(t) are amplified to saturation. Negative pulses are also amplified to saturation with the addition of an inverting stage so

that these output pulses are also positive. The output of such processing is shown in Figure 10. When $|e(t)| > \delta$, the output takes on the value $+V$ volts. When $|e(t)| \leq \delta$, the output is zero. δ is a small positive number representing the threshold level.

The output, $\gamma(t)$, may be mathematically defined as in equation 1.

$$\gamma(t) = \frac{V}{2} \{1 + \text{sgn} (|e(t)| - \delta)\} \qquad \text{eq. 1}$$

$$
\begin{aligned}
\text{where } \delta &= \text{threshold, } \delta > 0 \\
e(t) &= \text{amplified myoelectric signal} \\
V &= \text{d.c. saturation voltage} \\
\text{sgn} &= \text{sign function} = 1 \text{ if } (|e(t)| - \delta) > 0 \\
&\qquad\qquad\qquad\quad -1 \text{ if } (|e(t)| - \delta) \leq 0
\end{aligned}
$$

MYO-PULSE MODULATION

FIGURE 10.—In myo-pulse modulation the output, $\gamma(t)$, takes on the value $+V$ volts if the magnitude of the myoelectric signal, $e(t)$, exceeds the threshold δ. Otherwise it is zero.

Experimental results show $\gamma(t)$ may be used directly as an effective input voltage for proportional control of a d.c. motor. Each single pulse is sufficient to overcome "stiction" in the motor and drive system. Consequently, it is possible for single motor unit activity to produce output velocity. This action of a single motor unit is the smallest myoelectric signal which can create movement in the artificial mechanism.

Since only amplification is involved, there is essentially no time delay between input and output. As the myoelectric signal slightly precedes mechanical contraction of a muscle, it is possible for an artificial hand mechanism to actually respond more rapidly to a muscle contraction

than would the normal physiological hand. Smoothing is accomplished by the mechanical system instead of by electric networks. Kreifeldt and Yao have recently shown that some nonlinear detectors, particularly the quarter-root processor, have superior processing characteristics (6). The quarter-root processor has d.c. transfer characteristics which are similar to those of the myo-pulse modulation scheme described here.

2. *Synergetic Prehension*

To complement the improved myoelectric controller, a new type of powered prehension device was also devised. It was also disclosed during 1972 (5).

It is well known that essentially no power is required to operate a prehension device. Most of the time the fingers are either moving with velocity at no force or applying force with no velocity. Neither condition requires power.

The Vaduz hand and the Otto Bock electric hand (Z6) have automatic gear shifts so that the fingers are driven in "high gear" at good speed when not opposing a load, and so that they are driven in "low gear" when grasping an object. This approach is desirable, but the mechanisms tend to be complicated and may be slow in shifting back to "high gear" when it is desired that the mechanism should release the prehensile force.

We have suggested "synergetic prehension" as an alternative approach. In this approach two motors operate in a synergistic way to create effective prehension. One small motor and drive mechanism powers one set of fingers at high speed and low torque. The opposing thumb is driven by another small motor at slow speed and high torque. Thus, the former motor provides the speed for closing and opening the terminal device, while the latter produces high prehension forces. Each drive cannot be back-driven.

The principle of synergetic prehension is illustrated in Figure 11. Two electric powered hooks constructed on this principle are being used routinely by below-elbow amputees with good result. One of these fittings is shown in Figure 12. These terminal devices have maximum closing and opening speeds of 4.5 rad./sec. and prehension forces up to 90N (~20 lbf.). They release immediately at any load level.

We feel that the synergetic prehension idea as explained, or in other forms, is valuable in the design of prehension devices.
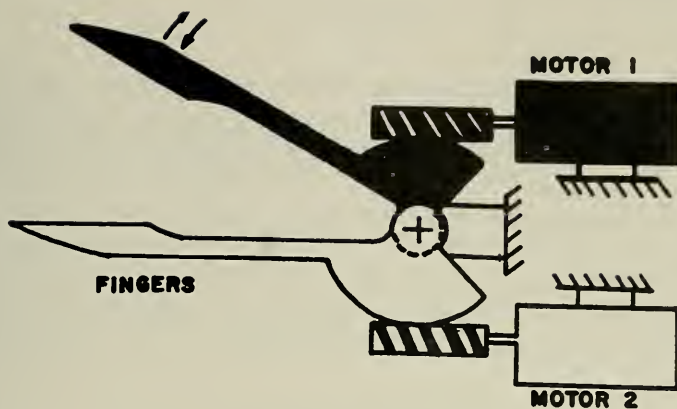
SYNERGETIC PREHENSION

FIGURE 11.—In "synergetic prehension" one motor and gear close the fingers while the other motor and gear create the gripping force. The motors function synergetically in the development of prehension.

FIGURE 12.—A below-elbow amputee wearing a "synergetic prehension" terminal device of the hook type. Myoelectric control self-containment and self-suspension are also employed.

SUMMARY

We believe that socket design is fundamental to the improvement of prostheses. Comfortable, well-fitted prostheses which are self-contained and self-suspended and which have an appealing appearance are basic to improved prosthetic acceptance. Engineering and scientific effort should be expended in the development of lightweight, reliable, and responsive mechanisms which are integral with these basic concepts. Likewise, control should be subconscious for the user and an integral component of the prosthesis. Consequently, prosthetics research and development requires a blending of scientific, technical, and medical ingenuity.

ACKNOWLEDGMENT

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STUDIES TOWARD A PRACTICAL COMPUTER-AIDED ARM PROSTHESIS SYSTEM

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INTRODUCTION

This paper summarizes a research and development program of the Biotechnology Laboratory, UCLA, that centers around the application of computer-based control techniques to the practical problem of externally energized arm prosthesis control. The impetus for this work is derived from the state of technology in microcomputer development which offers miniature implementable digital circuits. These capabilities provide a means for realizing advanced control schemes which involve on-line computation. Of particular interest is the use of this type of computer for auxiliary information processing to aid in the control task and reduce the control and information processing load of the patient. The objective of the work is the development of specifications and a prototype system which can be used by an amputee and which will aid him in the performance of a set of daily tasks.

In attempting to approach an advanced control system, the proposed work combines techniques developed in this laboratory with those of other research groups into an integrated package. The effort involves the establishment of the various interfaces between the subsystems and the fitting of each subsystem into operational use within the context of an externally energized arm package.

The following sections provide a brief description of each of the areas of work and summarize the progress to date.

EXPERIMENTAL ARM PROSTHESIS

Mechanical Construction

In the past year there has been a continuing effort to develop an

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experimental arm prosthesis from available components. The approach involves the selection of available individual joints, actuators, and the development of mechanical interfaces between the components. The objectives are: 1. To test the feasibility of integrating individually developed modular components into a single arm and 2. to provide a means for testing and integrating the control concepts which were developed in the Biotechnology Laboratory.

A first attempt resulted in a three-degree-of-freedom arm which utilized the AMBRDL hand, the AMBRDL wrist rotator, and the Northwestern University elbow unit. The arm was worn by an amputee and was used in experimental work, reported elsewhere by Lyman et al. (1). The arm was tested sufficiently to determine that it had clinical potential, but a major problem was found in the reliability of the components. In an attempt to solve these problems and increase the number of degrees of freedom of the arm, a new version has been assembled from a new set of components. The components, which were provided by the Veterans Administration, were the VA/NU hand, Northwestern wrist rotator, and VAPC elbow. In addition, a humeral rotator was designed and constructed from a modified VAPC elbow motor. As a variation to the use of the Northwestern wrist rotator (which proved to have inertial overshoot problems), the VAPC elbow unit was modified to serve all rotation purposes of the new arm. Simple modifications of the external shell of the elbow motor make it suitable to serve either as wrist or humeral rotator. This approach has created several advantages, including reduction in the number of different motors required, simplification of maintenance and repair, and reduction in cost of the arm if large production quantities become feasible.

At present two VAPC elbow units have been modified to serve as wrist and humeral rotators. The external gear assembly of the original VAPC motor shell was cut out and glued with epoxy into a specially constructed cylindrical shell. The motor core is then slipped easily into the new shell, and limit switches are installed on the shell cover. The modified shell can be made of any external radius to fit cosmetically either the wrist size or the humeral size. In addition, the shell can be constructed of lightweight plastic (PVC) or aluminum.

In order to provide position/velocity feedback directly from the motor assembly, the modification process included the implementation of resistive carbon material glued around the top part of the shell, and a roller installed on the motor shaft that travels back and forth on the carbon material to provide resistance variations as an indication of position/velocity.

The above modification process provides a completely self-contained, instrumented arm joint. Preliminary testing and evaluation demonstrated the superiority of the modified units to other components speci-

fically in the aspects of torque, precision, and control characteristics along with excellent cosmetic appearance.

Further work is planned to increase the reliability of the feedback potentiometers by using solid carbon cut to size, and evaluation of several other configurations for mounting the carbon resistance chips on the shell.

Additional recommendations concerning the design will be given at a later date when the system has been evaluated on some amputees under various environmental conditions.

All wiring is contained in the interior of the arm, and the components are not visible or exposed except for 2 in. at the elbow unit. Figure 1 provides an overview of the assembled arm.

Pressure sensors are installed on the fingertips of the VA/NU hand. The hand, in turn, is connected to the self-contained rotator modified from the VAPC elbow unit as described above. The VAPC elbow unit is then attached to the wrist by a skeleton frame covered by cosmetic rubber foam. A position feedback potentiometer has been attached on the shaft of the elbow motor and anchored to the skeleton frame. Finally, another self-contained rotator, to serve as a humeral rotator, is attached to the elbow.

SOCKET

PRESSURE FEEDBACK SENSORS

HUMERAL ROTATOR (1)

HAND

ELBOW MOTOR

WRIST ROTATOR (1)

FOAM RUBBER

FEEDBACK POT

(1) MODIFIED VAPC ELBOW MOTOR
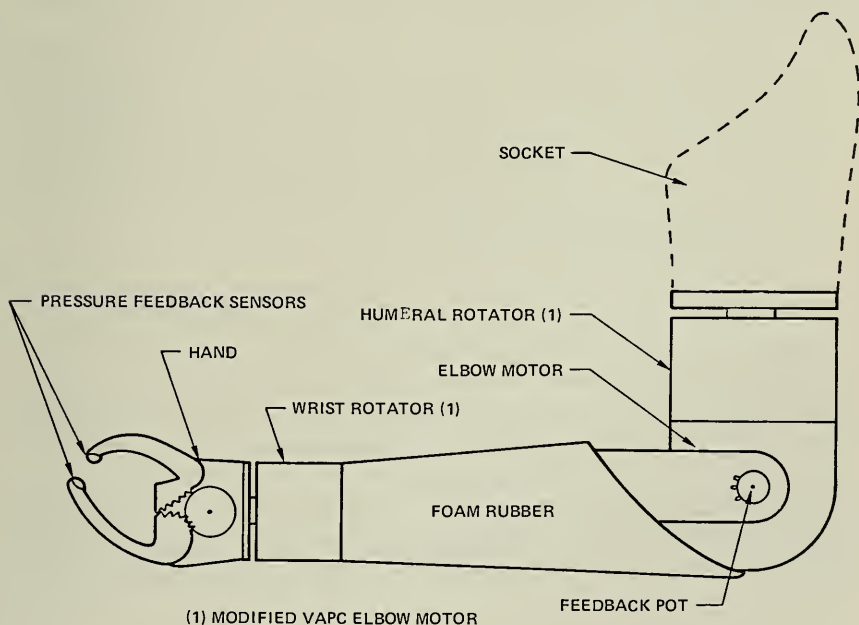
FIGURE 1.—Diagram of the artificial arm.

A digital to pulse width modulation (PWM) servo amplifier has been constructed and operates according to design specifications.

The digital to pulse modulation servo amplifier is believed to be the first practical prosthetic proportional controller which can be interfaced directly to a computer. Parts cost and size are relatively low because of availability of current technology.

Sensory Feedback

A fingertip pressure sensing system was implemented on the exper mental arm prosthesis in order to provide the operator/amputee with some sensation proportional to the pressure exerted by the fingers on various objects.

The purpose of this device is to decrease the amount of visual supervision required of the operator on the functions of his arm, and thereby reduce the attention and concentration required to perform standard operations.

. The project has proceeded on three parallel routes:

1. Implementation of a pressure transducer, connecting pressure to some variable electrical quantity to control the electronic network.

2. Implementation of information transformation system electronics in a design suitable to be mounted on the prosthesis.

3. Determination of method of stimulation. Several methods of stimulation were considered, including:

　　a. Skin stimulation by electrodes with choice of metal electrodes, conductive rubber, etc., in several configurations. Evaluation was made to determine the tradeoffs and advantages of several types of electrodes with special emphasis on resolution of sensation, amputee comfort, feasibility of implementation without interference with EMG signals, etc., and

　　b. Examination of possibilities of implanted stimulators activated either directly through the skin via vitreous carbon contacts or by induction. The experience of Dr. Frank Clippinger (2) and his group at Duke University is being monitored closely.

Work in progress is concentrated on the refinement of a pressure sensitive transducer, constructed in this laboratory from foam rubber doped with conductive materials and yielding variations in resistance-capacitance proportional to the exerted pressure. Evaluation of the electrical-mechanical characteristics of such devices as control elements for an electronic system simulating a physiological sensor has shown good potential. Figure 2 shows the characteristics of one configuration.
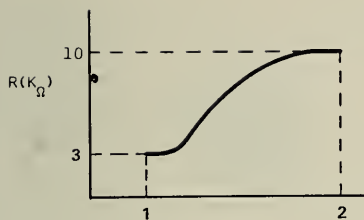
ΔX (~P) (cm) FIGURE 2.—Resistance deformation characteristics of the pressure sensor.

An electronic information transformation system, simulating a muscular sensing organ was designed and constructed.

Direct variations in resistance of the pressure transducer cause the information transformation network to increase the frequency of stimulation in the range of 10 to 120 pulses per second (p.p.s.). The pulses are 50 μsec. in duration and amplified by a step-up transformer to 250 v. in amplitude for skin stimulation. Capabilities exist for amplitude adjustment to a comfortable level for the subject.

Several electrode configurations were considered to interface the stimulating signal with the amputee. The purpose of the various types of electrodes is to eliminate pain/pinch effect felt by the subjects.

The following electrode configurations (as shown in Fig. 3) were designed, constructed, and tested:

1. Two round stainless-steel electrodes 2 cm. apart, mounted on flexible plastic base.
2. Concentric conductive sponge electrodes of several diameter sizes, installed in Plexiglas housing.
3. Two parallel cylinders mounted in Plexiglas housing.
4. Concentric metal electrodes installed in Plexiglas housing.

Evaluation of Various Electrodes

The rationale for testing various types of electrodes was to define the interaction of electrode size and material with the various parameters of stimulation, such as: resolution, pinch/pain, reliability of stimulation under various environmental situations, subject comfort, etc.

In the course of testing and evaluation, the following points became apparent:

1. Stimulation with conductive sponge electrodes resulted in reduced pinch/pain effect experienced by the subject.

A) STAINLESS STEEL — FLEXIBLE PLASTIC / STAINLESS STEEL

B) CONCENTRIC CONDUCTIVE SPONGE — PLEXIGLAS / CONDUCTIVE SPONGE

C) CYLINDRICAL ALUMINUM — ALUMINUM CYLINDERS / PLEXIGLAS

D) CONCENTRIC ALUMINUM — PLEXIGLAS / ALUMINUM ELECTRODES
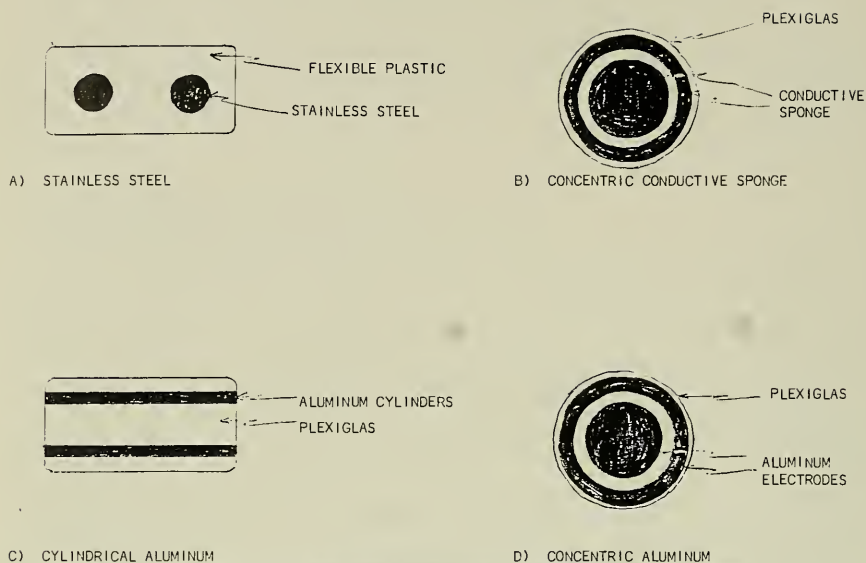
FIGURE 3.—Skin Stimulation Electrodes.

2. Larger diameter sizes of the central electrode also contributed to reduction of the pinch/pain sensation.

3. Stimulation with large electrode diameter caused localized stimulation in the skin area under the electrodes.

Close analysis of the various electrodes showed that the differences in the sensation felt by the subjects depend on several parameters, including:

1. Electrode diameter.
2. Contact area with the skin.
3. Amount of resistance introduced by the electrode material.

Since the skin could be taken as a medium into which an electric field is introduced, the electrical properties of the skin, along with the field strength, will eventually determine the sensation and comfort attained by any one electrode configuration.

The value of the electric field and the skin resistivity at its sensation threshold will determine the current density. It is the amount of current density that brings about the pinch effect, and increasing current density results in increased discomfort.

Another parameter to consider is the skin surface area which is in contact with the electrodes. As the surface area increases, the current density for a given fixed current will decrease. This will hold for the other electrode styles as well.

Still another factor to consider in the conductive sponge electrodes is the inherent resistance of the material itself. This added resistance contributes to limiting the current available, and therefore reduces pinch sensation.

The added comfort demonstrated by the conductive sponge electrodes is a direct result of the ability of the sponge to adjust itself to the skin surface curvature under slight pressure and therefore to increase the contact area.

It is clear from mathematical considerations that the added comfort provided by certain electrodes due to their geometry and material could be equivalently achieved by providing the stimulator network with proper regulation of voltage/current output for any electrical geometry. Fine adjustment of the powered output is necessary to achieve comfort for the individual to be stimulated, relatively independent of the electrodes used. Coarse output adjustment could compensate for simple electrical configurations.

The conclusion from this study is that electrode material and geometry should be considered for purposes of simplicity, cost, ease of the attachment and removal, shape of skin, etc. The comfort of stimulation and reduction of pain/pinch can be most easily achieved by power output adjustment.

Electronic Support System

The defined function of this system is to transform pressure information into physiologically meaningful coded signals. At present, the output of this system is dependent on the interface with the amputee. From our model and from experience evolved from this field in recent years (Reswick and Nickel (3)), it is well known that both skin and nerve fibers can be stimulated effectively by pulses of variable frequencies in the range between 10-100 p.p.s. Thus a reasonable requirement is that the system design contain a basic portion transforming the analog pressure information into pulses over the range of 10-100 p.p.s. The chosen interface with the amputee will determine the intermediate buffer network suitable for skin or nerve stimulation.

The system constructed at the Biotechnology Laboratory consists of the following components: pulse generator, frequency controller, and pulse width controller. The system is simple, and could be easily miniaturized for implementation in the socket or the forearm portions of the prosthesis; a power supply could be included.

A transformer was introduced at the output of the pulse generator to increase the strength of the pulses from 15 v. to 200 v., with a potentiometer output for adjusting the pulse characteristics for individual comfort.

COMPUTER-AIDED CONTROL

Background

An important aspect of the research and development on an adaptive aiding system is directed toward the specification of a software structure that can be implemented in a microcomputer, and used as an aiding device on arm prostheses. Computer aiding can be used in the following ways:

1. As an auxiliary control information source to supplement and aid the operator in the decision and control process, and

2. As an information transformation system which maps available patient control data into unique command signals in a manner compatible with operator capabilities.

The first type involves a parallel computer aiding where the computer generates control commands autonomously and can free the operator of part of the control burden.

The second type of computer function exists mainly in the direct control loop and provides computational transformation. Examples of this type of transformation have been used with end point and residual motion control (Whitney, 1970) and EMG pattern control (Wirta and Taylor (4) and Lawrence (2)).

Parallel Aiding

Parallel-type aiding has been realized by Freedy et al. (5) and has been the current focus of the Biotechnology Laboratory work. To date, a prosthesis-oriented adaptive aiding system has been developed and implemented on the Biotechnology Laboratory minicomputer. A recent, detailed description of the system has been provided by Lyman, Freedy, and Prior (1). The implemented system involves complete trajectory control and learning capabilities sufficient to acquire part of the control skill from the operator and take over that portion of the control.

The adaptive aiding system is based on an automaton that observes how the patient controls the arm and "learns" to take over a portion of the control responsibility. As the automaton takes over part of the control, the patient's control burden is reduced and performance improves. The system is implemented with a computer in parallel with the patient in the man/prosthesis control loop. The computer aids by making and displaying control decisions, and by supplying autonomous control inputs to the prosthesis control system. Adaptive aiding comes from a trainable "machine learning" algorithm programed on the computer. Prosthesis position and terminal device sensors allow the program to observe patient performance, and its results, and to optimize control decisions accordingly. The computer learns complicated control

strategies, can be pretrained for future tasks, and forgets unused actions.

The theoretical basis of the system is the maximum likelihood decision principle. It has been reviewed in several publications (Freedy et al. (5); Freedy, Hull, and Lyman (6)).

Advantages of adaptive computer aiding include:
1. The patient's information-handling load is reduced, enabling him to improve performance;
2. The patient concentrates on his most effective roles as initiator and supervisor;
3. The system provides an artificial means for removing part of the control function from the external visual control loop to an internal reflex loop;
4. The computer extracts task information from normal, ongoing, control actions;
5. The system concepts can be applied to various rehabilitative systems, at several levels of complexity; and
6. The system can be implemented with currently available minicomputers or microcomputers, and is therefore practical for current systems.

During the first year of the study, adaptive aiding for the generation of complete trajectory control of a prosthesis was implemented. Design modifications and improvements were introduced to the original actuator control system (Freedy et al. (5)). The basic principles of conditional probability and maximum likelihood remain, but the decision space and the input information have changed, and a new level of adaptability has been introduced.

SERIAL AIDING

EMG-Pattern Control Technique

The concept of EMG pattern control has recently become popular as a means for efficient and compatible control (Wirta and Taylor (4); Lawrence (2)). The philosophy behind the approach is the mapping of n electrode signal sources into m classes of patterns. Each pattern is used as a unique control signal to the arm. In this control scheme, signals from n control muscle sites are transformed into m prosthesis joint control signals. This is in contrast to the conventional control approach where control sites are uniquely linked to arm joints. The early success of the approach provided an impetus for testing the EMG-pattern control system as the control logic for operation with the computer-aided adaptive control system. The objective of this phase of work is to expand the application of EMG-pattern to end-point control; that is, to transform

signal from n signal sources into motion along m real world coordinates.

This was first done by Wirta's group at Moss Rehabilitation Center. In capsulated form, Wirta et al. (4), did pattern recognition work on the EMG signal generated by the anterior deltoid, posterior deltoid, middle deltoid, manubrial pectoralis major, upper middle trapezius, lower middle trapezius, lower trapezius, rhomboideus major, teres major, and infraspinatus correlated with arm motion. Data were gathered from a large number of normal subjects, the patterns found, and then used to control a prosthesis for an amputee, getting good control for humeral rotation, elbow flexion-extension, and forearm rotation. The amputee does not have to resort to articulated body English nor heavy concentration. Movements of the phantom limb correspond to movements of the prosthesis.

At UCLA, a slightly different approach to the same idea has been undertaken. Recognizing differences in EMG signals among individuals, different requirements of amputees due to level of amputation, etc., a system is being developed to measure ("learn" may be more apropos) a particular individual's EMG patterns and to create a personalized system. Rather than the subject being required to fit his EMG pattern to some standard, which does to some extent happen, the effort is being made at UCLA to fit the system to the amputee's peculiarities.

During a "learning" session (by which it is meant the system learns the amputee's EMG pattern, and not vice versa), nine EMG electrodes are attached to the amputee in the shoulder girdle region over muscles related to the amputated limb. In addition, an arm goniometer is fitted to the amputee's sound arm. Information from both sources is then fed into the laboratory minicomputer. The amputee is then instructed to move his phantom limb and sound limb in a parallel fashion; e.g., he extends both his phantom elbow and his sound elbow. While this is going on, the system watches the experiment and attempts to correlate the observed EMG pattern to observed arm movements. This phase of the learning session continues for 20 to 30 minutes, and is then stopped. The learned patterns are summarized in six probability matrices, which can then be transferred to the microcomputer that would ultimately be contained in the prosthesis.

Current experiments at UCLA with this system have been performed on a normal, nonamputated subject. The system has learned to move an arm prosthesis in the same manner as the subject moves his real arm after learning the EMG pattern for this subject. Experiments are scheduled for tests on an amputated subject in the near future. The system utilizes the Biotechnology Laboratory Interdata Minicomputer, an EMG amplifier, and analog to digital conversion equipment.

IMPLEMENTABLE MICROCOMPUTER

The principal objective of the work on an implementable microcomputer is to bring current development of computer-aiding control concepts and laboratory tested algorithms closer to clinical availability. This goal is approached through the application of the current state of technology in microcomputer developments which offer economically feasible miniature circuits of size and weight compatible for rehabilitation engineering applications. This state of technology has brought about the reasonable expectation of achieving a highly functional self-contained, self-supporting, externally energized computer-aided prostheses system for the mid to high above-elbow and shoulder-disarticulation amputee.

In the past, practical computer-aided prostheses have been physically impossible to construct. Several design limitations existed which precluded reduction of the computer and its power supply to a size and weight which would afford the amputee reasonable mobility. In addition, software programs previously developed for prosthesis control have been, at best, severely limited. This situation has recently been changed due to advances in microcomputer technology, as well as greatly improved control programs developed by our laboratory and elsewhere. The development of a practical, self-contained, computer-aided prosthesis is technologically feasible in the 1974 to 1977 period. Evaluation of the potential of this technology has led the Biotechnology Laboratory to perform a feasibility study for the utilization of microcomputers in prosthesis control (Lyman, Freedy, and Prior (1)).

This feasibility study, which was based on state of technology evaluation as of July 1973, has been completed. The objectives of the study were as follows:

1. To review the state of microcomputer technology and define available subsystems;

2. To recommend a specific microcomputer system suitable for controlling a prosthesis; and

3. To establish a preliminary design of a microcomputer-aided arm prosthesis.

Details regarding the results of the microcomputer study are given by Lyman, Freedy, and Prior (1). In the main, it was concluded that an electronic package for a four-degree-of-freedom above-elbow prosthesis, featuring pattern recognition of 10 EMG electrode sites as well as stored reflexes and autonomously generated subtask capabilities, could be placed in a 0.6-in. × 2.5-in. dia. package. The recommended microprocessor is the Teledyne series TDY-52 programable digital computer.

Included in the package would be a 51 instruction Control Processing Unit (CPU), 8,192 × 16 bits of Read Only Memory (ROM), 12,288 × 16 bits of Random Access Memory (RAM), 24-10 bit Analog to Digital (A/D) channels, and three servo amplifiers. Standby power drain is estimated at 192 mw, whereas all electronics would dissipate in the worst case about 5½ watts when the arm is in motion.

Using standard VA-powered components for the elbow and hand, plus VA elbows modified into a humeral rotator and a wrist rotator, sufficient energy from self-contained Ni-Cad batteries is expected to allow operation of the prosthesis throughout a normal day's activities. Programing of the Teledyne model TDY-52 computer can be accomplished from any standard teletype, remote terminal, or computer using an IBM 360 architecture. A comprehensive software support package is available from Teledyne.

Cost for the first prototype electronics package is estimated at approximately $7,900, whereas the 100 quantity price in 1975 should be less than $2,800. Electronic packages with fewer features (less memory, simpler CPU's, fewer A/D channels, etc.) are also available, with the cheapest costing about $500 in quantities of 100. The optimum performance versus cost tradeoff has not yet been established, although complete electronics packages useful to above-elbow and shoulder-disarticulation amputees are expected to add less than $1,000 to the cost of a powered prosthesis which does not contain a computer. The simplified package would also consume less power, thereby allowing the use of smaller batteries for the same wearing time.

TOWARD CLINICAL APPLICATION

In attempting to move the system to clinical applications, efforts are directed in three parallel paths:
1. Fitting the experimental arm prosthesis to a proper amputee subject.
2. Developing advanced EMG control schemes and their evaluation.
3. Integrating all hardware and software to form a practical arm prosthesis.

An amputee subject with high above-elbow stump was selected, and the socket-harness assembly is being prepared for him in cooperation with the UCLA Rehabilitation Center and the Sawtelle Veterans Administration Amputee Clinic. The subject is a machinist with good mechanical aptitude who is wearing the standard cable-controlled prosthesis. He is aware of problems associated with his prosthesis, and has made some changes in his terminal device to allow him to do several functions he could not do previously.

A series of experiments are planned which include;
1. EMG mapping to yield the best signal-emitting muscles;

2. Construction of a shoulder socket in which the EMG electrodes will be mounted permanently over the best EMG sites;

3. Learning and discrimination sessions to train the EMG adaptive-aiding system and the subject to perform a basic repertoire of motions that could be extended during use;

4. Evaluation of several control schemes such as the EMG pattern and aided control.

The culmination of the experimental sessions will be an evaluation study of the system hardware-software and the establishment of specifications that will include requirements for a microcomputer for integrating into a practical self-contained arm prosthesis.

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CONTROL OF UPPER-LIMB PROSTHESES IN SEVERAL DEGREES OF FREEDOM

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1. INTRODUCTION

This presentation deals with the state of the project of controlling an artificial upper-limb prosthesis in several degrees of freedom, conducted at Colorado State University, as of June 1974. It concerns work on the design and construction of a controller to control the above prosthesis by means of microelectronics circuitry and of microprocessor computational hardware. This presentation will describe the progress on two alternative aspects of the project which are also complementary to one another, since their combination can be employed to extend the number of limb functions to be controlled. These two aspects are: first, the toe-actuated controller and second, the EMG-actuated controller. Whereas the toe-actuated controller is already operational in our laboratory, in hardware, the EMG-actuated controller is presently in a simulation stage. Each of these controllers is presently a three-function limb-controller. However, both are in principle extendable to a higher number of limb functions. Furthermore, as stated earlier, both designs can be combined in a design having some limb functions controlled via the toes and others via myoelectric signals. This could be the case when both arms are amputated above the elbow, or when one foot is also not functional. Obviously, in cases where the amputee cannot use any toes, only EMG control will be considered.

We comment that the following research was started in November 1971, under a VA contract, and work on the EMG approach was initiated in July 1973, though some work on this aspect of the project was started already in January 1973. Involved in this research were, Dr. D. Graupe, Dr. W. K. Cline (until June 1974 on a part-time basis when he was a candidate and graduate assistant in our laboratory), Mr. T.K. Kaplon, M.S. (until January 1974 when he was an M.S. candidate and graduate assistant in our laboratory), and Mr. W. J. Monlux, B.S., since January 1974 (presently an M.S. candidate and graduate assistant in our laboratory). Mr. A.A.M. Beex, M.S., has joined our laboratory in July 1974, as a graduate assistant and Ph.D. candidate.

2. TOE-ACTUATED CONTROL

The toe-actuated controller designed at Colorado State University is now operational in our laboratory. It facilitates control of three limb functions, namely, elbow flexion, wrist rotation, and prehension. Continuous control of both position and speed or torque is possible up to prescribed limits, in either positive or negative directions, via pulse-width modulation. In contrast to an earlier toe-actuated control design, by S. Alderson (1) (1954), where three toe movements were required per limb function, the present design (2), employing logic techniques and microelectronic hardware unavailable in 1954, requires only one toe movement. Furthermore, the present design reduces to a minimum the complexity of actuation, as far as the amputee is concerned, and eliminates by parity-check logic computations and inhibitions, some most likely actuation errors.

Specifically, the toe-actuated controller employs actuation of soft (resistive) strain gages by means of the big and the little toe of each foot, noting that the above toes are noninteracting in their movement. Dead-zones in the strain-gage amplifier circuitry further avoid actuation by accidental toe pressure. Also, the system is inhibited during walking, thus facilitating control only while sitting, lying, or standing.

The strain gage signal is fed to the control logic which is in terms of a microelectronic integrated circuit. The latter coordinates the limb functions according to Table 1 [a] and computes inhibitions and parity checks for errors in actuation. (Modifications to this Table for cases of bilateral amputees, for amputees who have only the use of one foot, and for simultaneous actuation of two different limb functions have also been designed and are given in the appendices. Subsequently, the output of the control logic is fed to the appropriate permanent magnet d.c. motors to execute the control of the three limb functions considered, namely, elbow flexion, wrist rotation, and prehension. Hence, continuous position and speed or torque control up to a limit are facilitated at the positive and negative direction for each of the above limb functions (apart from the wrist rotation function, where speed control was not considered to be important).

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[a] Little toe movement can be replaced by a back movement (down) of the big toe that is different from BRD and BLD of Table 1, or by a movement of any one or more of the toes excluding the big toe, according to the amputee's convenience.

We comment that the above system is now complete in hardware form and includes the logic controller, the arm mechanisms, rechargeable Ni-Cad batteries, linkages, motors, interfaces, and special sandals with their toe-actuation strain gages, etc. The motors draw a maximum of 1 amp. at 18 v.d.c., the controller and actuators together taking only 3.5 mW. The whole system is packaged in a $5 \times 3 \times 1\frac{1}{2}$ in. box, excluding the batteries and the sandals with their strain gages, whereas the motors are housed in the arm itself. We also comment that there is no reason why other functions than those mentioned could not be exercised instead. Furthermore, noting Table 1, an extension to four limb functions is possible.

TABLE 1.—*Command Functions for Controller*

		Flex elbow			Extend elbow			Close grasp			Open grasp			Rotate wrist	
		F	N	S	F	N	S	F	N	S	F	N	S	CW	CCW
BR	U	X	X	X	—	—	—	DX	—	—	—	—	DX	—	—
	D	—	—	—	X	X	X	—	—	DX	DX	—	—	—	—
BL	U	DX	—	—	—	—	DX	X	X	X	—	—	—	—	—
	D	—	—	DX	DX	—	—	—	—	—	X	X	X	—	—
LR	D	—	—	—	—	—	—	—	—	—	—	—	—	X	—
LL	D	—	—	—	—	—	—	—	—	—	—	—	—	—	X

Key:
BR: big right toe
BL: big left toe
LR: little right toe
LL: little left toe
U: (press) up
D: (press) down

N: normal speed
F: increase speed (or torque, force)
S: decrease speed (or torque, force)
X: press (close switch)
DX: press after delay (such that X precedes DX)
CW: clockwise
CCW: counterclockwise

3. EMG-ACTUATED SUBSYSTEM

Whereas the system of Section 2 employs toe movements as input actuation signals to the prosthesis controller, the controller is not limited to just this kind of input. Also, not in all cases will that kind of input be available, since cases of injury or paralysis of one or more toes or feet may occur. The natural input actuation sources for control at will are thus myoelectric signals.

Major problems in multifunctional prosthesis control via EMG signals are filtering the EMG signals from noise (environmental, EKG, etc.) and from other interacting EMG signals, as well as the problem of recognizing (separating) the EMG signals related to different limb functions. For adequate and reliable solution of such filtering and recognition, a rigorous statistical analysis of EMG signals is required. Unfortunately, the EMG analysis in the literature is mostly restricted to ad hoc methods of spectral density and correlation evaluations (3, 4, 5, 6, 7, 8, 9, 10, 11). Hence EMG prosthesis control was essentially of single-function nature, and the resulting multifunctional control was thus always of ad hoc nature, employing amplitude-level coding (12). This in turn has usually required level-training of the amputee to actuate multifunctional control to affect reliability and amputee's comfort. Methods of pattern recognition of EMG signals were recently proposed (13). However, these have involved a large number of electrodes and complex memory and computation regarding ad hoc and usually predetermined tasks to again affect reliability, simplicity, comfort, and speed. Noting the recent advances in applying rigorous time-series analysis techniques to EEG analysis (14, 15, 16), a similar but non ad hoc philosophy has been proposed by this author for application to EMG signals (17, 18, 19, 20). These advances, coupled with the enormous advances in microcomputer and microprocessor hardware, form the basis for this work and for its reliability with today's hardware.

The present approach to EMG analysis recognizes the nonstationary nonlinear nature of the EMG signals. Furthermore, it recognizes the practical constraints in any realization of filtering and identification or recognition, when employed in conjunction with a realistic prosthesis, the constraints being those of time available for processing and of cost and weight of computational hardware to be carried by the amputee (say, in his pocket). These constraints must and do certainly lead to compromises and to simplifying assumptions in any analysis, that will detract from the rigor of the analysis. However, via using microcomputer hardware, an adequate and reliable solution based on rigorous analysis is still realizable as long as the number of degrees of freedom considered is small. (An incorporation of the latter system with limb control as in Section 2 (2, 18) thus leads to considerable prosthesis maneuverability via EMG-actuation, while causing hardly any mental strain to the amputee in terms of a need to learn complex actuation combinations, etc.)

The present analysis has been based on the nature of time-series. Their pattern can be parameterized into a finite set of parameters of a linear signal model (16), which forms a reduced minimal set as compared with the (almost) infinitum of values of the pattern itself. These parameters need not all be stationary or unique per each function for

function separability. However, if at least some of these parameters will be such that their range of variation for a given limb function does not overlap with that of other functions, then such separation will be possible; this was found to be the case in all our surface-electrode EMG recordings (over 250 records).

Specifically, noting the constraints above, we have decided to examine minimum-order autoregressive-moving-average (ARMA) models of stationary time-series (16, 21, 22, 23, 24, 25, 26, 27). Although the EMG signal is not a stationary one, we have shown (see Table 2 and References 18, 19, and 20) that the signal is sufficiently stationary per each of the limb functions considered, to yield ARMA parameters whose range of variation with time is adequately small to facilitate discrimination of these limb functions (elbow flexion, wrist rotation, and prehension). The choice of a minimum-parameter linear ARMA model is thus justified by its yielding the required function discrimination and noting that the identification of a nonlinear or of a nonstationary model is impossible in practice, especially since for practical actuation of limb functions, the identification and the recognition of a function must be completed within about 0.1 second.

Although in the case of Table 2, separation is already possible when considering only one electrode location, this may and need not be the general case. However, if we wish to resolve different limb functions, we may generally have to record EMG signals at several (few) locations, such that *at some of these locations at least some of the parameters of the various functions* do not change in time so much that these functions become indistinguishable. Further results obtained have all facilitated similar function separation.

TABLE 2.—*ARMA Model for Recorded EMG—Ranges of Parameters*
s=10; Electrode at Biceps

	$\hat{\phi}_1$	$\hat{\phi}_2$	$\hat{\theta}_1$	$\hat{\theta}_2$	σ_w^2 ($\times 10^{-3}$)
L1, F1	$-.8923\pm.1120$	$-.0809\pm.1230$	$-.0700\pm.0880$	$-.0817\pm.0631$	$4.388\pm.261$
L1, F2	$-1.801\pm.0480$	$+.8517\pm.0160$	$-.4635\pm.210$	$-.2023\pm.025$	$1.213\pm.265$
L1, F3	$-1.906\pm.010$	$+.9354\pm.013$	$-.0303\pm.290$	$+.3111\pm.016$	$2.152\pm.690$

Key: F = Limb Function, L = Electrode Location, σ_w^2 = Variance of model residual, s = Order of Autoregressive Model, ϕ_i = Autoregressive Parameters, θ_i = Moving Average Parameters

Results based on 10-bit EMG data

We comment that the parameters considered above need not be similar for equivalent functions of different patients. To overcome this problem, complete offline identification (to establish parameter ranges) must be made for each patient prior to connecting his prothesis-controller to the identification and filtering microcomputer that is to execute the recognition.

Obviously, since external or biological non-EMG noise (say noise due to motors, fluorescent lights, etc.) may have overlapping parameters, this should be filtered first. The latter filtering is presently accomplished by using an optimal-linear Kalman filter based on the ARMA parameters above as identified from the recorded EMG data without any a priori knowledge of ad hoc assumptions. We note that EKG interactions may be filtered out by employing special low-band EKG filters.

Whereas all our results have been obtained from processing EMG data on the Colorado State University CDC 6400 computer, we have also completed a preliminary design of the microcomputer hardware required for on-amputee computation and control. Furthermore, a simulation study based on using INTEL 8008-1 and 8080 microprocessors is underway, employing a double length word (16 bits in total), noting the fixed point arithmetic features of that hardware. This preliminary study indicated that with presently available INTEL eight-bit fixed point hardware and double length words, all computation can be completed within 0.1 seconds. This is in fact within our real time needs. However, noting that fixed point arithmetic reduces somewhat the accuracy, a floating point system is certainly most desirable. Since INTEL and other companies have already announced a 16-bit microprocessor equivalent to the present INTEL 8080, but which is 16 times faster (1.25 μs instruction time), an incorporation of a floating point routine in this microprocessor hardware is possible within the constraint on computation time. Hence, our goal of 0.1 second total time, with accuracy as achieved on the CDC 6400 computer for our data from the 10-bit analog-digital converter (see Table 2), will be met when this hardware is marketed in early 1975. Furthermore, since our INTEL simulation program is usable to directly program the microprocessor hardware (namely, to produce hardware as required for our purpose), and noting that very similar if not fully identical programs can be used for the faster microprocessors, our work should not only establish the feasibility of our approach considering the constraints on cost, speed, performance, and weight that are obvious in real prosthesis hardware, but also should actually produce this prosthesis-borne EMG processing hardware.

4. CONCLUSIONS

The work that has been described concerns a multi-functional artifi-

cial upper-limb controller. The design was based on actuation via toe inputs and via EMG inputs. Whereas the toe-actuated system is presently complete and merely requires on-amputee testing and the related modifications, the second actuation system is only at a design stage. However, even the latter has already been proved to be feasible for realistic prosthesis application by processing of real data with microcomputer hardware, and it awaits computation and adjustments of false alarm probabilities, and of concrete hardware realization (with hardware to be available in early 1975 but which is in principle similar to existing, though somewhat slower, hardware). Consequently, a multi-functional arm using the controller of Section 1. with either toe or EMG actuation or both, for controlling three to six limb functions, should be complete by the end of the present project.

We cannot help emphasizing the importance of the recent progress in stochastic filtering and estimation software and theory and, above all, in microcomputer hardware, to achieve this end. We believe that microcomputer hardware must and will play a major role in artificial limbs and organs and in bioengineering diagnostic and surgical systems, due to its enormous computational power encapsulated in small and cheap hardware. This should be of tremendous benefit to the disabled and to the sick, opening new avenues in treatment, diagnosis, and in artificial and semi-artificial limbs and organs.

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APPENDIX I—DESIGN MODIFICATION FOR CASES OF DOUBLE AMPUTATION
(BILATERAL ABOVE-ELBOW AMPUTATION)

In this modification, the design is modified to allow elbow flexion, wrist rotation and prehension of each arm in both directions (up or down or clockwise and counterclockwise), as in Table 2, to facilitate actuation of two upper-limb prostheses in cases of bilateral amputees.

<div align="center">TABLE 1</div>

FUNCTION		RIGHT ARM	LEFT ARM
ELBOW — FLEX		BRU	BLU
ELBOW — EXTEND		BRD	BLD
PREHENSION — OPEN		LRU	LLU
PREHENSION — CLOSE		LRD	LLD
WRIST ROTATION — CW		BRU AND BLU	LRU AND LLU
WRIST ROTATION — CCW		BRD AND BLD	LRD AND LLD

KEY:
BRU - BIG RIGHT TOE UP
BRD - BIG RIGHT TOE DOWN
BLU - BIG LEFT TOE UP
BLD - BIG LEFT TOE DOWN
LRU - LITTLE RIGHT TOE UP
LRD - LITTLE RIGHT TOE DOWN
LLU - LITTLE LEFT TOE UP
LLD - LITTLE LEFT TOE DOWN
CW - CLOCKWISE
CCW - COUNTERCLOCKWISE

Comments

In this design a total of six functions are controlled (in two directions each).

No speed control is facilitated.

Control is continuous via pulse width modulation.

All other toe combinations than in table above are inhibited to disallow errors in actuation.

Cases of one above- and one below-elbow amputation can be accommodated via small (simplifying) modifications in the design.

Simultaneous use of right and left arm is possible.

Simultaneous actuation of elbow flexion and prehension and of wrist and prehension is possible.

APPENDIX II—DESIGN MODIFICATION FOR CASES
OF ONE-FOOT-DISABILITY

In this modification only one foot can be used, such that an upper-limb amputee who cannot use one of his feet can still actuate the toe-controlled upper-limb prosthesis.

TABLE 2

FUNCTION		TOE ACTUATION
ELBOW FLEXION	FLEX	BU
	EXTEND	BD
PREHENSION	OPEN	LU
	CLOSE	LD
WRIST ROTATION	CW	BU AND LU
	CCW	BD AND LD

KEY: CW— CLOCKWISE
CCW— COUNTERCLOCKWISE
B— BIG TOE
L— LITTLE TOE
U— UP
D— DOWN

Comments

In this design only one arm is controlled (three functions, two directions each).
Otherwise a combination of EMG- and toe-control must be used.
All other actuation combinations are inhibited.
No speed control is possible.
Modifications of the three degrees of freedom arm for cases of *shoulder disarticulation* are also similarly possible when speed control is eliminated or when LRD, LLD are used for shoulder movements.

APPENDIX III—SIMULTANEOUS ACTUATION OF TWO LIMB FUNCTIONS

The design of Table 1 of the main text can be modified to facilitate simultaneous actuation of elbow and/or grasp and/or wrist movements. These are facilitated by modifying Table 1 such that speed control is eliminated, and the actuation scheme of Table 3 is followed.

In that case, a joint actuation of BRU and LRD or of BLU and LLD is inhibited, and only BRU or BLU alone are executed. Note that Table 4 relates to a right-arm prosthesis. In the case of a left-arm prosthesis, R and L of Table 4 should be interchanged.

TABLE 3

Function		BR		BL		LR	LL
		D	U	D	U	D	D
Prehension	Close	X					
	Open		X				
Wrist	CCW			X			
	CW				X		
Elbow	Flex					X	
	Extend						X

STATUS OF THE JOHNS HOPKINS RESEARCH PROGRAM ON UPPER-LIMB PROSTHESIS-ORTHOSIS POWER AND CONTROL SYSTEM

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INTRODUCTION

The application of external power and advanced control system technology to artificial limbs has resulted in the development of an assortment of electrically powered hands, wrists, and elbows. Certain types of power units have been developed exclusively for elbow motion, whereas others have been developed exclusively for wrist motion and/or terminal-device function. Therefore, in order to actuate both elbow and terminal device, or elbow, wrist, and terminal device, more than one power unit is required. Furthermore, conventional prosthetic manufacturing techniques and components must be extensively modified in some cases to be compatible with some of these power control units.

As an alternative to the design of specialized externally powered devices, the Johns Hopkins approach has been to develop a basic power pack and control concept which has much versatility relative to application to upper-limb prostheses as well as possible application to orthoses. Two sizes of motor power packs and three types of sensors have been evaluated in selected experimental clinical testing. The sensor options are myoelectric, skin displacement, and body motion inputs. These basic components can be assembled in a number of ways to meet a particular requirement. The motor/electronics/battery pack may be located on the belt and power transmitted to the local area of need by means of a Bowden cable, or the power unit and battery unit may be located integral in the prosthesis.

The principal merits of this system are:
1. It utilizes many standard, available, prosthetic components.

2. It allows actuation of more than one joint, e.g., elbow, wrist, and terminal device, by a single motor and single myoelectric or skin displacement site.

3. Control is proportional and easily learned.

4. System has been shown to be durable and reliable.

5. Component placement is optional. Powered components may be located either on the prosthesis or worn on the belt to optimize the system to individually suit the amputee's needs.

6. Full VO terminal-device interchange capability is retained.

7. It permits the patient to override the power unit manually without mechanical damage.

This system concept is currently undergoing clinical evaluation under the direction of Dr. G. Schmeisser, Chief of Orthopedic Surgery, Baltimore City Hospitals, on 10 amputees and two paralytics. Since the program was initiated in 1969, powered systems have been fitted to one wrist-disarticulation amputee, three below-elbow amputees, two elbow-disarticulation amputees, four above-elbow amputees, three shoulder-disarticulation amputees, two paralytics with flail elbows, and one paralytic requiring a hand orthosis. One of the shoulder- disarticulation amputees is a bilateral congenital amelic.

Preliminary results of clinical evaluation have been published in the Bulletin of Prosthetics Research in BPR issues 10-16 through 10-19 (Fall 1971 through Spring 1973). The results from this evaluation demonstrate the reliability and usefulness of this powered system approach, especially for amputees with higher level amputations.

DESIGN CONCEPT

A block diagram of the system concept is shown in Figure 1. Input signals can be provided by one of three means:

1. Single-Site EMG Sensor

For those patients who have a suitable EMG site available, a packaged electrode assembly/electronic preamplifier may be utilized to provide proportional control of the power unit. This control mode was found to be most useful for amputation levels up to and including the above-elbow. A typical application of this sensor is shown for the below-elbow case in BPR 10-18, p. 264. The power unit for this system is worn on the waist. This particular patient cannot tolerate conventional harnessing on the opposite shoulder due to skin graft condition and is an ideal patient for this type system.

The use of EMG control for an above-elbow prosthesis has been examined and found to be of merit, particularly for long above-elbow cases with good EMG signals. Extended work envelope and ease of control are two of the merits for this application.

PROSTHETIC CONTROL SYSTEM
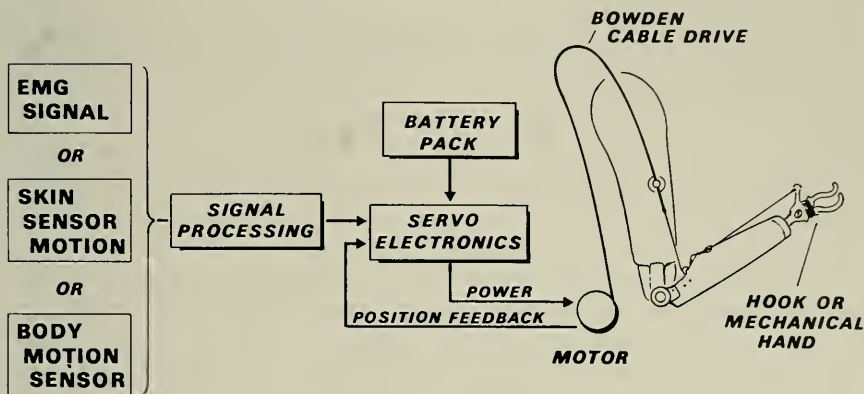
FIGURE 1

2. Low Force Level Shoulder Control

Patients with a short above-elbow amputation appear to be prime candidates for the use of low force level shoulder control of a displacement transducer located within the prosthesis. The stump at this amputation level is generally too short for adequate contact surface in the conventional prosthesis, and the typical high force levels required for conventional prostheses cause additional unwanted motion of the upper portion of the prosthesis. Conventional systems fitted to amputees of this type are usually abandoned after little or no use.

EMG sites were explored on such patients and satisfactory sites could not be found. It was then decided to use gross body motion similar to body-powered systems but reduce the stroke requirement to 3/4 in. and force requirement to less than 2 lb. These requirements were met by using body motion to control a spring-loaded position transducer located within the prosthesis. External connections to this cable are identical to conventional practice for a figure-8 harness as shown in BPR 10-21, p. 131. Elbow unlocking was accomplished by means of an electromechanical arrangement that reduces the unlocking force level on the harness to an acceptable low value relatively independent of load on the prosthesis. The elbow is automatically locked approximately 2.5 sec. after first motion of the arm.

The control technique of using low force level shoulder control has been applied to two patients for a test period of several months. This

technique appears to provide a practical way of controlling the powered prosthesis for hard to fit cases.

3. Skin Motion Sensor

For higher level amputations, such as shoulder disarticulations, the harnessing of skin motion has been found to be practical and useful input command. A low force level motion 'transducer has been developed and is incorporated in the shoulder-disarticulation powered prosthesis shown in BPR 10-20, p. 264. Less than 3/4 in. of lateral skin motion over the pectoralis muscle allows proportional control of the motor to control elbow or terminal device opening. Control of shoulder motion (0 deg. and 45 deg.) is achieved by a chin nudge switch located on the shell of the prosthesis. The power unit for this prosthesis is located in the elbow space. Tests with the skin motion sensor input have been conducted over a 2-year period on one patient with highly satisfactory results. These tests are continuing to further evaluate the powered prosthesis.

MOTOR-ELECTRONIC COMPONENTS

The basic power and control components utilized in the Johns Hopkins system may be seen in BPR 10-19, p. 214. The motor is a direct-drive low-speed (15 to 20 r.p.s.) d.c. torque motor. It is coupled to a two-stage 15 to 1 gear reduction in the output stage. This system permits actuation in less than 1 sec. to torque levels of 13.6 kg. cable force and weighs less than 0.5 kg. It is so quiet that it is almost inaudible. The power units have no clutches, brakes, or mechanical stops and are very reliable; there have been no malfunctions or mechanical failures. They can be stalled at full power for short periods of time without internal damage of any kind. Hence, no current-limiting circuits are required.

The electronic control cards utilize discrete electronic components on printed boards. Reliability of these circuits has been excellent.

The removable nickel cadmium battery packs are conveniently sized and designed to allow the average user from 4 hours up to a full working day per charge. A diode was placed across each cell to minimize reverse polarity effects when the cells run down. A small charging unit recharges one or two packs simultaneously and shuts off automatically after 3 hours.

In addition to the basic development and evaluation program being conducted at Johns Hopkins, a complete set of drawings and specifications of the basic Mod 1 unit has been forwarded to the VA Prosthetics Center in New York. These drawings were submitted to industry for bids by the VA Prosthetics Center in New York for limited production. A

contract for six above-elbow units was awarded by the VA to the Pope Brace Company, Kankakee, Illinois. The system components include a myoelectric signal sensor or body motion input transducer, drive motor, control electronics, battery pack, and forearm pulley assembly.

The units have been delivered and are undergoing final engineering acceptance testing with preparation being made to fit these units to suitable above-elbow amputees (see BPR 10-19, p. 216).

POWERED ORTHOSES

In parallel with the development of powered systems for upper-limb prostheses, applicability of these concepts to orthoses is also being investigated.

One possible application is the use of the external power pack/cable arrangement to power a flail elbow. Our first patient, who had bilateral unstable flail shoulders and elbows, assisted in the early tests of basic system concepts but later withdrew from our evaluation program because he could achieve no useful function from the elbow flexion appliance. Part of the problem stemmed from the scapulohumeral joint hyperextending as the elbow flexed. Since the patient could not reach out in front of him, he could find no significant merit to the system. The progression of the design was from an initial complex harnessing arrangement with an external mechanical hinge, an intermediate design using lightweight cloth strap arrangement on both the forearm and upper arm, to a final arrangement which supports the cable housing by means of an attachment to a suspenders-type body harness and continues to use the lightweight cloth strap forearm arrangement (see BPR 10-20, p. 326).

A second paralytic patient, now in his 7th month of evaluating the elbow flexion device, had originally sustained a brachial plexus injury resulting in a flail scapulohumeral joint and total paralysis of elbow flexors. He had an adequate triceps, good scapulothoracic control, and good hand and wrist control. Surgical fusion of his scapulohumeral joint gave him good shoulder control; therefore, his residual disability was limited to lack of active elbow flexion. As anticipated, the improved powered elbow flexion device has operated well in this situation. Figure 2 shows this system fitted to the second patient. Proportional control of the elbow orthosis is achieved by use of the EMG sensor located near the elbow on the forearm.

A third paralytic patient undergoing evaluation has flail shoulders and elbows, bilaterally. He has no active muscle power in the left hand and wrist. Although his left biceps muscle lacks useful power, it generates a myoelectric signal. This patient's paralysis is a result of infantile poliomyelitis; hence, he has no sensory impairment. Furthermore, because of the underdevelopment of the digits and thumb web space of his

left hand, attempts to fit him with an orthosis designed to oppose the thumb and first two digits were unsuccessful. Careful analysis of his existing functional capabilities and needs revealed that he used the fingers of his right hand very capably for manipulating objects, but he needed some means of carrying objects in his left hand which did not depend on its digits. The clasping device was developed for this purpose (see BPR 10-21, p. 134). This patient uses his biceps myoelectric signal to control the power unit mounted on the forearm shell. The motor opens the appliance. When he relaxes, spring tension closes the palmar shell against his palm. He has now been using this device for about 4 months. It is easy for him to apply and is inconspicuous when covered by his shirt sleeve. It is performing as intended and is proving useful in his work activities. Evaluation of this device will be continued.

CONTROL INPUT SENSOR DEVELOPMENT

One of the key elements in a powered orthosis or prosthesis is the interface sensor between the patient and his machine. Three sensor techniques have been exploited in the Hopkins research program and were described earlier in this report.

During FY 1973, work was initiated on integrating a small magnetic diode within the frame of eyeglasses and placing a small high energy magnet on the skin near the eyebrow area. Tests in the laboratory on an experimental model have demonstrated that proportional control can be achieved with little training (Fig. 3). The technique looks sufficiently

promising to warrant further investigation for possible application to quadriplegics for control of power devices. A second sensor device (a small accelerometer) is also being investigated for use with the eyeglass frames. Preliminary tests indicate there may be signals related to audio sounds, such as teeth clicking or temporo mandibular joint motions, to provide on-off function control (see BPR 10-21, p. 135). Preliminary results from tests with these devices indicate that proportional control is achievable by locating the very small magnet over the eyebrow and using eyebrow motion for control. The second sensor, a small accelerometer located on the eyeglass frames, picks up the sharp vibration pulse caused by teeth clicking with the mouth closed. An electronic detector-filter circuit provides good rejection of unwanted signals. This technique is currently being evaluated on the patient wearing the powered elbow orthosis. It provides a means of turning the EMG signal on/off to allow the patient full use of his hand without inadvertent motion of the elbow.

FIGURE 3

A powered orthosis manipulator controlled by the eyeglass sensor is now under construction. This device is designed to provide the functions of hand grasping, elbow flexion, shoulder motion, and turntable motion for a highly disabled wheelchair or bedridden quadriplegic. The system employs two standard motors and control electronics utilizing mechanization techniques developed for the powered prosthetic systems described elsewhere in this report. Mode-select and on-off control is provided by means of the teeth-clicking joint motion as sensed by the accelerometer on the eyeglass frame. The patient can select any one of five modes of control by this means. Proportional motion of the output can be achieved by either an EMG signal on the side of the forehead or by eyebrow motion sensing using the magnetic motion sensor located on the eyeglass frame.

FUTURE PLANS

Engineering and development will be continued on the basic sensor interfaces in addition to total system integration of powered orthoses and prostheses. Clinical evaluation of experimental models will provide qualitative data on system performance and will aid in the identification of areas requiring further development.

Electrical Stimulation

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Electrical stimulation is of growing importance for a variety of fields, partly as a result of the SRS support of developments in Yugoslavia and partly as a result of both basic research and clinical trials under various sponsors in this country. Electrical stimulation not only is used for muscle activity but also has implications for providing sensory feedback, for tissue healing after amputation surgery, and for healing decubitus ulcers. Thus electrical stimulation may prove useful for spinal cord injury in addition to the possibilities of muscle stimulation.

Perhaps some day electrical stimulation also will have clinical applications for artificial hearing and vision. There is a clear interrelationship between these areas, which goes beyond any given narrow specialty.

Dr. Clippinger of Duke University was unable to come to the conference, but he and his associates have provided a paper. Dr. Clippinger has been active in providing a below-elbow amputee with electrical feedback via the median nerve in the forearm by means of an implanted electrical stimulator. The frequency of stimulation is proportional to the prehension force applied by a split mechanical hook.

In the electrical stimulation field, it is appropriate to know something more about surgically implanted electrodes—their longevity, their influence on the body, and the influence the body has on them. A small project with the UCLA Brain Information Service is making a critical survey of literature on surgically implanted electrodes, not only in amputees but also in all sorts of other applications. This survey has been done, under the guidance of Dr. Chase, by Dr. Margaret Babb of the Brain Information Service, with Dr. Anthony Dymond as a consultant. Dr. Dymond, formerly at UCLA-BIS, is now at the Brentwood VA Hospital, in the Los Angeles area. (Dr. Dymond will make the oral presentation. He and I also had organized two informal conferences on surgically implanted electrodes for the American Society for Testing and Materials.) The Los Angeles group found that vast amounts of

literature are available showing tremendous inconsistencies as well as diversity of designs and variety of applications. The real problem is to make some sense out of the various apparent disagreements.

Although Professor Pierre Rabischong of Montpellier, France, was unable to attend the conference, we are publishing a paper in two parts in this issue describing the experiments on electrical stimulation of muscle which he and his colleagues are conducting at the Biomechanics Research Unit 103 of the French National Institute of Health and Medical Research (INSERM). Professor Rabischong is professor of anatomy at the University of Montpellier with interests in biomechanics and spinal cord injury. Among his associates are orthopedists and neurosurgeons, as well as electrical and control engineers from the Unit and the Faculty of Sciences. While somewhat similar experiments have been conducted elsewhere, it is rather difficult to find results, particularly on isotonic loading; some results have been presented only in progress reports to sponsors or as abstracts of oral presentations at conferences. It is also illuminating to know of the French references he cites. The Montpellier carbon fiber electrodes appear novel. The work published represents independent study by these investigators, aimed at reducing the clinical problems resulting from spinal cord injury.

Dr. Cochran of St. Luke's Hospital in New York has been using electrical stimulation in experimental animals to try to accelerate bone healing after deliberate creation of defects in long bones. He is also associated with the Helen Hayes Hospital at West Haverstraw; he recently reported in BPR 10-20 (pp. 29-61), experiments on wheelchair cushions.

A SENSORY FEEDBACK SYSTEM FOR AN UPPER-LIMB AMPUTATION PROSTHESIS

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A project to provide sensation from an upper-limb amputation prosthesis has been underway at Duke University since early 1971. This was initially made possible through the generosity of Mrs. Carlton Hooks of Thomasville, North Carolina, who provided funds for a pilot study. Since December 1, 1972, the project has been aided by contract from the Veterans Administration with an expected termination date of November 30, 1975.

Providing sensation for the amputee from his prosthesis has been a challenge for many years, but until recently there has been no practical solution. Function of the normal hand is dependent on sensory feedback. In addition to information regarding imminent injury, calibration of force of grasp and pinch, recognition of the shape of an object, and knowledge of the position of the hand in space contribute largely to the dexterity that we take for granted.

The traditional prosthesis that we have supplied for the upper-limb amputee does not have this capability. The amputee must receive much of this information by visual contact and the remainder through pressure changes between his stump and the socket and between his skin and the harness. There is no intrinsic sensory feedback from his terminal device which he must use as an anesthetic tool.

Biceps cineplasty used with voluntary closing hook did provide some additional information, as pressure between the fingers could be calibrated by interpretation of pressure changes between the surface of the tunnel and the peg. Cineplasties have not been acceptable widely in the

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United States, however, because of the difficulty in maintaining the skin in good condition within the depths of the tunnel.

Another partial solution is the split forearm or Krukenberg amputation with which objects can be grasped between the radius and the ulna. This has been recommended primarily for blind amputees in whom function is negligible in a conventional prosthesis and the unacceptable cosmesis is not a great handicap.

During the past 25 years, there have been several attempts to provide the amputee with a sensory mechanism.

Wilms and Siehlow (1) in Liechtenstein in the early 1950's trained amputees whom they fitted with electrically motored prostheses to correlate their phantom sensation with motion and function.

Beeker, During, and den Hertog (2) reported from Utrecht, Netherlands, in 1966, a prosthesis in which a signal from a piezoelectric crystal deformation, after amplification, was delivered to the patient through skin electrodes as a shock. This apparently is an on-off system without proportional control.

In 1968, Pfeiffer (3) at the Sepulveda Veterans Hospital and Rhode and Fabric at the Augusta Veterans Hospital developed a pressure transducer and applied it to thumb and forefinger covers in insensitive hands. This delivered information to the patient through an auditory signal using a hearing-aid earpiece. There is no record that this system has been used in an amputation prosthesis.

Since the middle 1960's, Alles, Mann, and others (4, 5, 7, 8, 9, 10, 11, 12, 13, 14, 15) at the Massachusetts Institute of Technology have been working with sensory feedback systems using mechanical or electrical input systems to remote areas of the patient's skin or via a hearing-aid earpiece to the ear. The concept was developed originally for the purpose of providing information as to the position of the MIT-Liberty Mutual myoelectric elbow.

In 1969, Kawamura and Sueda (6) at Osaka developed a prosthesis for below-elbow amputees in which a mechanical vibrator stimulated the skin at the end of the stump within the socket. This was a proportional system with the rate of vibration being controlled by an amplified signal from a strain gage transducer in a modified voluntary opening Dorrance hook.

Miniaturization of electric circuits and components has made possible the development of small electrical devices that can be implanted in the human body. Mooney (6) at Rancho Los Amigos Hospital has used an implanted induction-powered radio receiver-pulse generator for motor stimulation of the peroneal nerve in hemiplegic patients. Nashold (7) in the Division of Neurosurgery at Duke University has also used a similar device to stimulate the spinal cord or peripheral nerves for control of intractable pain. After review of these projects, it seemed likely that this

type of system could be used to produce sensory stimulation from the terminal device of a prosthesis if the following criteria could be met:

1. The electrode would be placed on the median nerve, and the mental image should be that of the peripheral cutaneous distribution of that nerve—the thumb, index, long, and half the ring finger.

2. Voltage must be sufficient to produce a stimulus, but not at a painful level.

3. A transducer in the terminal device must be capable of varying frequency related to activity.

4. The entire system, including the amplifier, transmitter, and power source, must be small enough to fit within the prosthesis to avoid extraneous wires, battery packs, etc.

5. The system must be sufficiently durable to withstand normal use of an amputation prosthesis.

6. The design must be such that the patient can don and adjust it one-handed.

The implant designed by Avery Laboratories was selected (Fig. 1). This is an inductively coupled RF receiver, small enough to implant in the arm, measuring 2.9 by 0.9 cm. It is tuned to 2.05 MHz ±5 percent and the capability is 0-25 V. and 0 to 400 Hz. It is embedded in biocompatible epoxy and is encased in Silastic. A Silastic sheet skirt incorporating Dacron mesh is attached.

The skirt is used to suture the unit to the fascia to prevent migration. The output of the implant is a capacitively coupled pulse producing a zero net direct current flow in the nerve at rates and amplitudes that are determined by the external transmitter.

FIGURE 1.—Receiver unit in place in subcutaneous pocket.
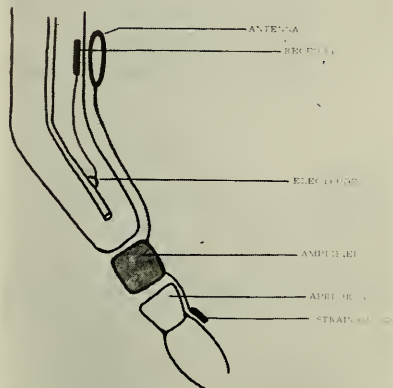
FIGURE 2.—Diagram of sensory feedback system.

Figure 2 illustrates diagrammatically the feedback system. The initial patients would be below-elbow amputees to minimize the mechanical problems of prosthetic use. The implant is placed subcutaneously in the medial aspect of the distal arm, away from interference from any part of the prosthesis. The prosthesis would be activated in a conventional manner using a Figure-8 harness and cable control. It is necessary, if pressure is to be varied, that a voluntary closing terminal device be used. An APRL hook with the locking cam removed was selected. While this would force the amputee to "hold on" to an object, it was felt that this was a normal function, and removal of the cam would eliminate the additional force and subsequent pressure increase necessary to unlock the hook.

Two patients who had had the implant inserted and attached to the median nerve in the forearm for the treatment of phantom limb syndrome were available for study. On stimulation, both described a paresthesia referable, as expected, to the peripheral distribution of the median nerve—the thumb, index, and long fingers. In both patients, the power could be adjusted to a comfortable level and both could distinguish very small changes in frequency between 0 and 100+ Hz. This implied that the basic concept was correct.

The present project calls for a trial of the system on 15 patients; 10 below- and five above-elbow amputees. To date, 10 patients—eight below- and two above-elbow amputees—have had the implant inserted and seven have been fitted with prostheses. Surgery has required 2 days hospitalization.

SURGERY

In the below-elbow amputee, general anesthesia and tourniquet hemostasis were used. A 2½-in. incision is made over the (Fig. 3) medial aspect of the arm above the elbow and the subcutaneous tissue is separated from the superficial layer of the deep fascia, forming a pocket large enough to accommodate the receiver. The plexus of superficial veins that lies on the fascia is not disturbed.

A second incision is made over the volar surface of the forearm, the muscles are separated, and the median nerve identified, usually at the level of the distal border of the pronator teres muscle. The distal portion of the nerve is not dissected free and the distal neuroma is not disturbed or resected.

A subcutaneous tunnel is made between the two incisions. The receiver is placed in the pocket above the elbow and the electrode fitting and the lead wire are passed to the distal incision. To prevent migration, the skirt on the receiver is attached to the underlying fascia with three or four sutures of 3-0 Mersilene.

The electrode fitting is passed around the nerve and the flanges (Fig. 4) are sutured together. No sutures are placed in the epineurium and the fitting is just snug enough on the nerve to insure electrode contact.
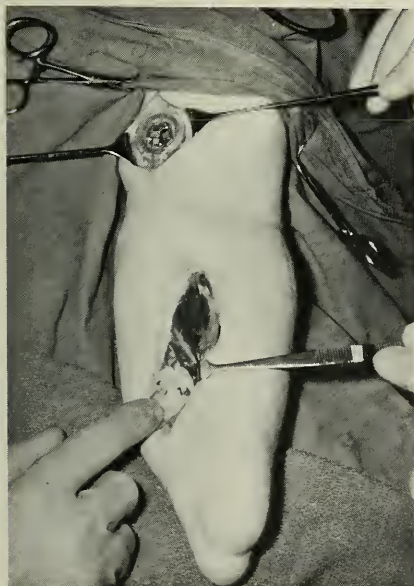
FIGURE 3.—Receiver and electrode in forearm at surgery. The lead wire has been passed subcutaneously between the incisions.

FIGURE 4.—Electrode receiver and electrodes on the median nerve.

Excess lead wire is coiled and placed between the muscles, the tourniquet is released, any bleeding is stopped, the wound is closed and a compression dressing is applied.

Following removal of the sutures, the patient is allowed to resume activity wearing his old prosthesis.

To date, there have been no wound complications. One patient had an area of ecchymosis over the volar side of the forearm. This resolved without problem.

TESTING RESPONSE

All patients have been tested at the time of suture removal using a precisely calibrated stimulator box from the dorsal column stimulator system. Table 1 outlines the patients and their statements regarding response. This is totally subjective and one has to rely on the patient's individual interpretation and his ability to communicate it. All implants have functioned satisfactorily. In most of the below-elbow amputees, visible contraction of the median nerve supplied muscles in the forearm has been observed. This becomes tetanic at about 35 Hz. All patients have had a threshold which produces a tingling paresthesia that they have stated is not uncomfortable at a power level of 0.8 V. or less, and this has been referred to at least a portion of the sensory distribution of the median nerve in the hand. Variations in the mental image are felt to be due to differences in orientation of the electrode on the nerve. As the frequency is increased, the paresthesis perceived increase in frequency to blend into a constant paresthesia at about 35 Hz. Above this level, the sensation changes, described as being either a mental image of fist clenching or a change in distribution of the paresthesia — other fingers appearing. Above 100 Hz. two patients state that sensation disappears, the others describe a vibration again.

One patient says that his hand feels as though it is within his stump. All the others perceive the hand at about normal length and position. When they attempt to pronate and supinate the forearm, the hand follows.

None of the patients has experienced a change of threshold or response since the implant was inserted. There has been nothing so far to suggest a change in resistance or impedance across the nerve or significant development of perineural fibrosis.

THE PROSTHESIS

The prosthesis fitted is a conventional limb with double wall socket, triceps pad, flexible elbow, Northwestern Figure -8 harness and cable

control (Fig. 5). The terminal device is an APRL hook with the locking cam removed and fitted in reverse, with the thumb on the ulnar side of the forearm. This has been done to accommodate the transducer and prevent it from being subjected to repeated trauma across the face of the socket. The transmitter antenna is secured to the arm over the implant with Velcro straps.

FIGURE 5.—Type II prosthesis with APRL hook, strain gage in the cable and electronics packet in the forearm.

ELECTRONICS

The transducer is a strain gage bridge. In the first prosthesis it was mounted on the base of the stationary finger of the APRL hook. This had the advantage of producing a stimulus with push and pull activities as well as grasp, and the patient apparently enjoyed the fact that he could adjust the system so he could rub his hook lightly and feel it. However, in this position, the transducer is quite vulnerable to damage and requires a complex protective cover. In addition, the deviation at this point is both lateral and rotary producing a somewhat erratic response.

In the subsequent prosthesis, the strain gage has been mounted in the cable system where it is protected, and the force is linear.

A spring-loaded on-off switch is fitted into the end of the transducer housing. When the prosthesis is not being used or the cable is slack, the system is off, thus preventing constant battery drain.

The electronics package is mounted on a stainless steel (Fig. 6) chassis which incorporates a curved cover plate fitted with a snap lock door for access to the battery compartment and adjustment screws. Figure 7 is a diagram of the electronic system. The power source is a 9V. transistor battery which in use has a life of 4 to 6 weeks and is easily and inexpensively changed.

TABLE 1

Patient	Age	Diagnosis	Implant	Threshold	Response
1	36	Left BE	5/15/71	0.7V	0-35 Hz - Increasing vibration 35-100 Hz - Fist clenching 100 Hz+ - Vibration
2	30	Left BE	2/72	0.5V	0-35 Hz - Increasing vibration 35-100 Hz-Long finger→ index→ thumb→ ring 100 Hz+ - Vibration
3	47	Right BE	12/29/72	0.7V	0-35 Hz - Increasing vibration 35-100 Hz - long→ index→ thumb flexing 100 Hz+ - Vibration
4	27	Bilat. BE Blind	2/73	0.7V	0-35 Hz - Increasing vibration 35-200 Hz - Initially hand swelling - after 2 weeks, fist clenching 200 + Hz - Vibration
5	25	Left Be Right BK	10/9/73	0.8V	0-35 Hz - Increasing vibration 35-90 Hz - Flexion thumb, index, long 90 Hz+ - Decreasing signal
6	23	Bilat. BE	12/6/73 (right)	0.5V	0-35 Hz - Increasing vibration 35-100 Hz - Index-long, thumb flexing 100 Hz+ - Loss of signal
7	21	Right BE Severe hand deformity, left	1/22/74	0.8V	0-35 Hz - Increasing vibration 35-100 Hz - Fist clenching 100 Hz+ - Decreasing signal
8	44	Right BE	6/29/73	0.6V	0-35 Hz - Increasing vibration 35-100 Hz - Increasing tightness of index, long, thumb 100+ Hz - Decreasing vibration
9	19	Left AE	8/2/74	0.9V	0-35 Hz - Increasing vibration 35-80 Hz - Paresthesia long— index— thumb 80+ Hz - Vibration

FIGURE 6.—Type III electronics package.
presently in use.

BLOCK DIAGRAM, TRANSMITTER

Type III
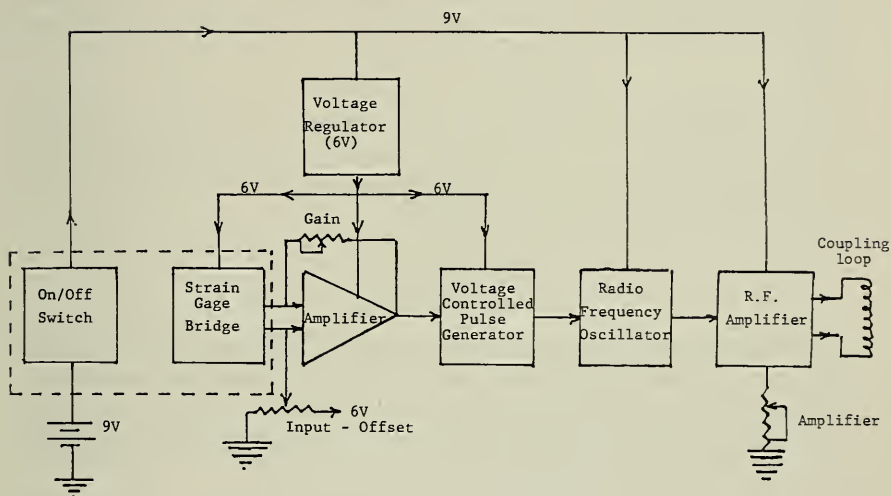
FIGURE 7

The entire electronic system, including the antenna and strain gage, can be removed for service and a new unit inserted and adjusted in a few minutes.

In use the sequence of events is as follows:

The first ⅛ in. of cable travel turns the system on; further cable travel closes the hook until it touches some object or the other finger. At this point, the strain gage is activated and stimulation begins which increases in frequency proportional to the increase in force.

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PROSTHETIC RESPONSE AND ACCEPTANCE

The subjective response to stimulation has been essentially the same with the prosthesis as with the testing equipment. The only major variation is that several patients have volunteered that they not only perceived the amount of pressure they are exerting but also the consistency of the object they are squeezing—soft, resilient, or hard. Presumably, these patients are correlating the cable travel with the rapidity of the increase in frequency. This was an unexpected finding, although Kawamura and Sueda (6) reported a similar response in patients wearing their vibrating system.

None of the patients has had a problem converting to a voluntary closing hook, nor have they complained of the necessity to "hold on." Without a lock in the terminal device, length of the forearm-hook complex is important, and some patients have had a problem with secure grasp close to the body such as handling their trouser buttons, belt, and zipper.

Thus far, none of the patients has abandoned the system, although one is considering it, as he says the time required for service interferes with his business. He has not, however, been fitted with the removable and replaceable unit as yet. He has an intermediate electronics package which has had a maintenance problem.

PROBLEMS

The biggest problem has been related to the APRL hook which is too bulky and too long. A smaller terminal device is needed and such is under development at present. This is a conversion of a Dorrance hook to a voluntary closing capability by means of a return spring mounted in the hub. It should be available by the end of 1974.

The size of the electronic package produces some limitations, particularly for amputees with long stumps. Ultimately, subminiaturization would be advantageous.

The entire system including battery weighs 220 gm. This has not been a disadvantage, although it is mounted in the distal forearm. Subminiaturization would also produce weight reduction.

Electronics failures in the present unit have been related to excessive wear of the wire leading from the strain gage to the electronic pack in the forearm. Three failures have occurred, necessitating repair. There have been no implant failures.

FUNCTIONAL TESTING

Comparative functional testing between the conventional prosthesis

and the sensory feedback system has not been done. This is planned for all subjects between December 1974 and November 1975. A protocol is being developed and the results will be incorporated at the time of our report.

SUMMARY

1. Early results suggest that the concept is correct; that nerve stimulation with resulting appropriate interpretation and mental image can be obtained by use of an implanted induction powered nerve stimulator and at voltage levels that are comfortable.

2. A proportional control can be obtained and interpreted, and the system can function as a prosthetic replacement for the missing end organ and nerve.

3. Further experience is needed for the above-elbow amputee.

4. A new voluntary closing terminal device is needed and is being developed.

5. Testing needs to be done comparing function with sensory feedback with that obtained with a conventional prosthesis.

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SURVEY OF IMPLANTED ELECTRODES[a]

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Many types of electrodes are being used today for a wide variety of clinical purposes. Interest has focused on these electrodes, or more specifically, the electrode-tissue interfaces, because they constitute the true junction between the living tissue and the equipment being employed to study it. Whether the electrodes are being used to monitor potentials or to pass currents, their properties influence the interaction between the equipment used and the physiological system being confronted. Both the effectiveness of the attempted procedure and the actual safety of the patient depend upon our understanding the properties of the electrodes being used.

For example, much effort has been expended on developing electronic stimulators with well-controlled and isolated outputs, in order to safely and effectively present stimuli to the body. Yet, if these stimuli are delivered through an electrode of inadequate size, configuration, or material, or if the stimuli have inappropriate parameters, the stimulation may be ineffective in achieving the desired physiological results, and, at worst, may be actually injurious to the patient. Even in the case of passive recording of bioelectric potentials with adequate amplifiers, there exist possibilities for error and insult, since all metals must by thermodynamic necessity release some ions into the surrounding tissues, as well as interfacing with physiochemical elements capable of catalyzing nonbiological chemical reactions. These factors may, over time, result in perturbations of the normal physiological behavior of the surrounding tissues or of producing changes in the physical properties of the electrodes themselves.

A survey of clinical applications of electrodes reveals little consistency of usage. A variety of electrodes have been implanted in many different regions of the body, for varying lengths of time, though the tendency is

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toward longer durations. They are fabricated from a wide range of materials in a variety of sizes and configurations, and the techniques for their implantation and anchoring differ. When electrodes are used for stimulation, the parameters of the applied pulses differ widely. Undoubtedly, these inconsistencies will be further compounded by the increasing use of electrodes by a growing percentage of clinicians and by the proliferation of new techniques and materials in electrode use.

A critical review of clinical electrode applications at this time will, therefore, serve several practical purposes. It will provide a survey of the various factors involved in electrode applications and will allow a comparison and evaluation of these factors, so that it will be possible to determine the best methods presently available to accomplish specific clinical objectives. It will serve to define the areas in which electrodes are now used, and to identify the areas which are currently the most active. It will help to project future developments. In addition, it will serve to improve communication between workers in this field.

Our review is being carried out through the Brain Information Service at UCLA. The survey of implanted electrodes is based on a comprehensive search of the literature which started first with the Brain Information Service data tapes. This was followed by a full Medlars search and searches of the data bases from the Bioresearch Index and from Biological Abstracts. Compendix was also searched, as was the Defense Documentation center. This latter source would produce the "AD" type [Astia Document, Astia now changed to NTIS] references. Odd and even Chem Abstracts and the Government Reports Announcements data tapes were searched, as were those from SPIN, the tapes from the American Institute of Physics, and NASA. Finally, selected bibliographies were solicited from a number of workers.

The search of these ten computerized data bases is completed and has yielded slightly over 10,000 references. These have now been screened and categorized, and the bibliography itself is finished. The review is presently being written. This will be introduced by a discussion of the properties of the electrode-tissue interface which influence electrode behavior, and the ways in which various electrical waveforms passing through the interface affect it. The review will then deal successively with electrodes used for monitoring bioelectric potentials and with electrodes used to pass current. Since at present a major area of emphasis concerns stimulation, the greatest detail of the review will be placed here.

Each section of the review will deal specifically with the questions of what is being attempted, what techniques are in use, and what successes and failures are being encountered. The final section will deal with new materials and techniques which may play a significant role in future electrode technology.

ELECTRICAL STIMULATION OF LIMBS

PART I. — BASIC STUDIES

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SUMMARY

This report is concerned with experimental work on the nervous stimulation of the agonist muscles governing the movement of a single joint of a dog's foot (ankle). Such stimulation will determine if it is possible to control smoothly the movement of the joint and the forces developed by these muscles.

Previous studies analyzed the muscle either at rest or during tetanic contraction. The data presented here are concerned with the mastery of muscular contraction. The ultimate goal is ability to produce artificially, after spinal cord injury, a rapid contraction to oppose exactly an external force or to attain a desired new position and to maintain that force or position without fatigue. The present paper reviews selected literature and describes electrodes and stimulators. It then reports certain studies on isometric contraction. Useful forces are found at frequencies of 30-50 Hz for application of rectangular pulses to the motor nerve leading to the anterior tibial muscle of an anesthetized dog. The influences of pulse amplitude (millivolts) and of pulse width (microseconds) on force are studied. For each there is a rather rapid but largely linear rise from threshold to saturation.

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INTRODUCTION

There has been considerable research on the contraction of striated muscle and its relations with the central nervous system. Hill (1) (1938) and Huxley (2) (1957) carried out fundamental studies to obtain better knowledge of the phenomena and ultimate structures of muscle in order to explain its behavior during a voluntary contraction—altogether three classes of muscle models have thus been proposed:

1. The visco-elastic model: Voigt (3), Levin and Wyman (4) (1927), Hill (1) (1938), Pringle (5) (1961), Caspi (6) (1969), Pertuzon (7) (1972), and many others, describe characteristics that are really valid only during tetanization. They do not explain the transient phenomena.

2. The calorimetric model of Hill (1) (1938) relates the coefficient of "muscle load-reducing velocity" to the measurement of heat exchange in the muscle. But these results are difficult to use.

3. The physico-chemical model of Polissar (8) (1952), Goodall (9) (1957), Huxley (2) (1957), with which it is difficult to give an explanation of the muscle mechanical properties.

The objective of all these different models is to explain muscle behavior during voluntary contraction. This report describes a different approach to the problem. We use a normal muscle-nerve unit (without any physiological, physical, or chemical lesion) in which the possibility of voluntary contraction has been suppressed by cutting the spinal cord. The nerve root exiting near the spine or the peripheral nerve near the muscle is stimulated electrically to make the muscle contract. The results are intended to determine if it is possible to develop a model of a muscle adapted to optimal control, that will lead to artificially controlled movement in a paraplegic patient.

METHOD OF APPROACH

Means of Muscle Excitation

A muscle will only contract when it is exposed to a certain stimulation. This may be of chemical, thermal, mechanical, or electrical origin. The signals naturally transmitted by the nerve and motor end plate are of the electrical kind. Variation of the distribution of ions (or charges) and the resulting field potentials propagate along the nerve. The easiest method to alter this distribution of ions is to use electrical stimulation.

Three solutions to the electrical stimulation problem are commonly used. With external stimulation, signals can be transmitted to the muscle by electrodes applied on the skin (3). This method, however, has three main disadvantages:

1. It is necessary to have a good external spatial location of the muscle to be excited.

2. There is a risk of exciting several muscles at the same time (parasitic excitations of nonselected muscles).

3. High potential drive signals are necessary.

Direct stimulation of the muscle, by placing electrodes in direct contact with the muscular mass itself, also has three main disadvantages:

1. The electrical signal strength required for a good contraction is relatively high.

2. The reproducibility of the phenomenon mainly depends on the position of the electrodes.

3. There is a risk of very quickly exceeding the fatigue threshold of some muscular fibers.

Direct stimulation of the nerve (10) is very tempting since the nerve/motor-end-plate/muscle unit works as a strong energy amplifier with a gain that may reach 10^6. The propagation of a signal along a nerve is analogous to the propagation of a signal by an electric line; a difference in potential (due to an unbalanced distribution of the charges in the nerve fiber) spreads along the nerve with a given velocity. The phenomenon is not sensitive to the location of the stimulating electrodes on the nerve, but only to their separation. Because of the low intensity stimulation required, the stimulator may be small, and therefore its chronic implantation is feasible. [b]

Nervous stimulation can be carried out at several levels. Stimulation on the muscle nerve directly poses a problem because there is an afferent proprioceptive sensitive nerve contingent. During stimulation, signals from these sensor fibers may create inopportune reflex contractions, as well as possible painful sensations in a patient, with an incomplete lesion of the spinal cord. In addition, stimulating on the common nerve trunk may excite several muscles at the same time.

Stimulation at the level of the nerve root exiting from the spine seems to be the best general solution to the problem, since the ventral nerve root leaving the spine has only motor fibers and to each radicle corresponds a definite muscle (or a very small group of muscles). In spite of surgical and experimental difficulties concerned with the determination of radicular topography, such a stimulating technique may be considered in the future.

In the experiments reported here, we stimulated the muscle nerve directly since it is the easiest to use and since during experiments carried out under anesthesia, we are not impeded by the secondary firing of sensor nerve fibers.

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[b] In this article, we will not enter upon the implantation problems nor upon the chronic stimulation (nervous or muscular). Researchers such as J. B. Reswick, Rancho Los Amigos Hospital, Los Angeles, Calif., have already solved them in particular cases.

Choice of Stimulating Electrodes

When a nerve is stimulated with metallic electrodes, a cell effect, due to the mobility of the ions in an electrolytic medium, can be seen. This polarization appears very quickly, either preventing any nerve stimulation or making the muscle contraction phenomena unreproducible. Polarization is annoying since it alters the signals we want to send to the motor-end-plate. Corrosion soon appears at the electrodes (even if they are made of noble metal) (11).

In order to circumvent these problems, we use stimulating electrodes of pure carbon fiber. The advantage of this material is that it is a relatively good conductor and nonpolarizable. Moreover, it is well tolerated by the system, judging by the attempts carried out by P. Rabischong and his colleagues on dogs over periods of several months. This material, manufactured in the form of fabrics (woven threads) as well as casting, has given very satisfying results.

We have developed a stimulating technique using two woven carbon fiber loops which we very loosely ligate around the nerve. To avoid spreading of exciting signals in the noninsulating tissues near the nerve, a silicon insulator surrounds the ligatures (Fig. 1). This system was successful because with the stimulating amplitudes we use there is no spreading detectable in the neighboring tissues.
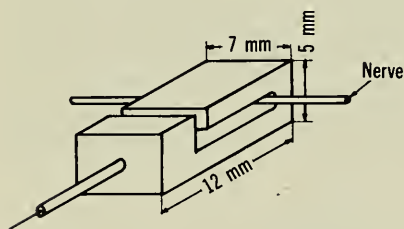
FIGURE 1.—Diagram of a stimulating electrode.

Electrical Stimulator

Let us approach now the problem of the form of the stimulating signal

which we want to send into the muscle nerve in order to initiate a muscle contraction. We know that to control a voluntary muscle contraction, the motor nerve transmits a signal composed of frequency modulated impulses. We therefore built a low output impedance transistor stimulator which delivers rectangular impulses [c] whose amplitude, width, and frequency can be regulated independently. Analog signals proportional to these three parameters are available for recording.

Two versions based on the block diagram shown in Figure 2 were developed. [d] One is a laboratory stimulator directly integrated with a hybrid computer. The other is a portable version (120 mm. × 80 mm. × 20 mm.) that runs with batteries. It is possible to modulate separately the amplitude, width, and frequency of the pulses, sinusoidally at a variable low frequency.
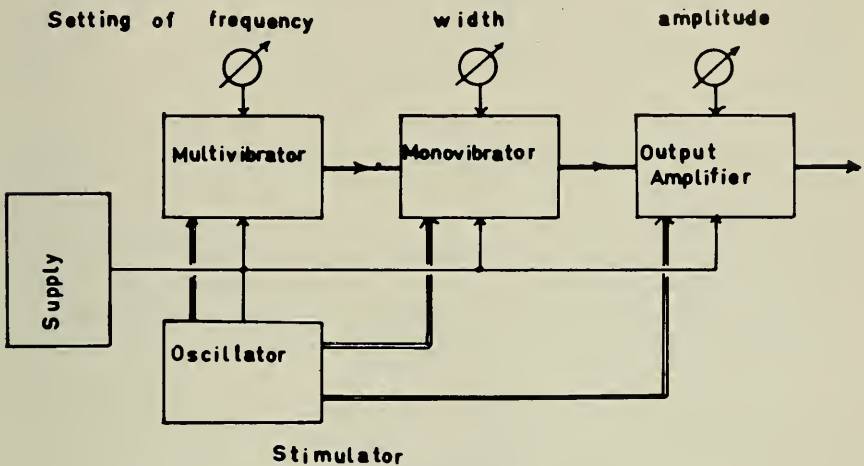
FIGURE 2.—Diagram of a stimulator.

Muscle Response Measurements

We studied the muscle response by measuring displacements and strains to which a limb is submitted by a single pair of muscles (agonist and antagonist). In the present state of our study, we were mainly interested in three parameters:

1. The force (or torque) developed by the limb.
2. The angle of rotation of the limb.

[c] We use rectangular-shaped impulses, but considering the present state of our study, we cannot say whether this is the optimal shape.

[d] The stimulators generate rectangular impulses with a rise time of less than 1 microsecond (μs), at a rate between 0.1 and 60 Hz, and pulse width between 10 and 2000 μs. The amplitude is between 0 and 4V or up to 80V with an external stimulator; usual values in these experiments were 60 to 500 millivolts (mV).

3. The force exerted by the tendon of each muscle.

The experiments were carried out on the paws of dogs. The agonist muscle is the anterior tibialis and the antagonist is the triceps surae. These muscles control the rotation of the ankle. The plan of the experiment is given in Figure 3.
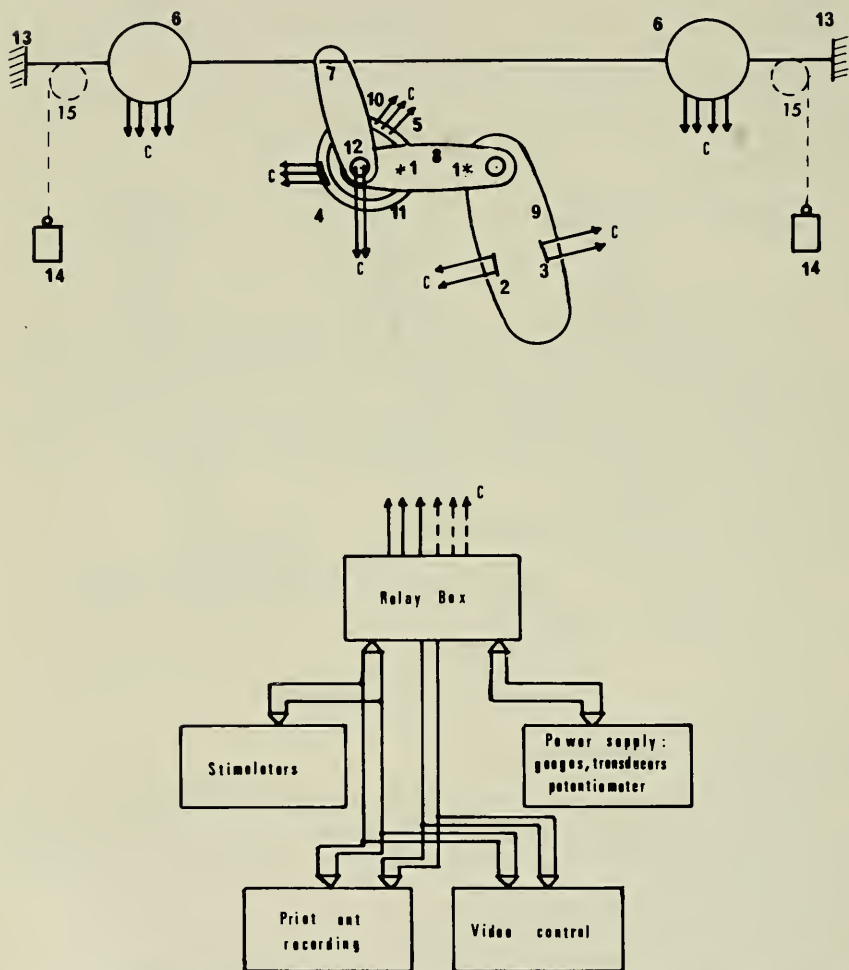
FIGURE 3.—Synoptic diagram of the experimental setting: 1. orthopedic pins through the tibia, 2. stimulating electrodes on the external popliteal sciatic nerve (tibial control), 3. stimulating electrodes on the internal popliteal sciatic nerve (triceps nerve), 4. JFET transducer included in the triceps tendon, 5. JFET transducer included in the anterior tibial tendon, 6. metallic gauges bridges, 7. foot, 8. calf, 9. thigh, 10. flexor M1—anterior tibial, 11. extensor M2—triceps, 12. potentiometer enabling measurement of θ, 13. attachment for isometric tests, and 14. setting with weight for isotonic tests.

The force developed by the limb is directly measured with a ring on which are attached four bridge-connected metallic strain gauges. The working principle is given in Figure 4. A voltage varying linearly with force F, reported in kilograms force (Kgf), is obtained.

Measurement of strain
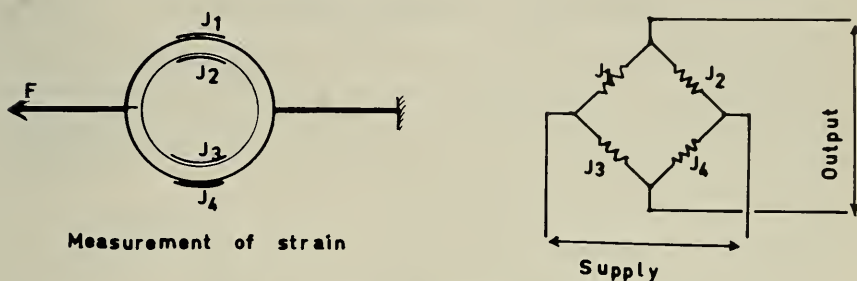
FIGURE 4.—Diagram of a metallic gauges transducer.

The force developed by a muscle may be measured by tendinous transducers: there are semiconductor gauges (JFET) with a volume near 0.2 mm^3, surrounded by an insulating material and bound up in the tendon by insertion inside it. The magnitude of the voltage is approximately proportional to the muscle force. (The first attempts were carried out by P. Rabischong et al., 1965 (12), on tendons, with transducers of another nature.) The difficulties now lie in the testing and mainly the method of attaching these transducers which must not irreversibly damage the tendon.

The angle of rotation of the limb is measured by a potentiometric system with negligible friction which gives the joint angle independent of the position of its apex and the plane of rotation.

Experimental Procedure

After deep general anesthesia of a selected dog, the surgeon isolates the internal and external popliteal sciatic nerve or a hind leg and fixes the stimulating electrodes and the insulators. He inserts the JFET transducers in the anterior tibialis and the triceps surae tendons. After ascertaining that the muscle can be stimulated and that the tendinous transducers are functioning, the wounds are resewn. In order to maintain the calf in a firm position, two orthopedic pins are fixed through the tibia and secured in a metallic frame fastened to the operating table. If isometric measurements are made, the foot is maintained at a fixed angle with regard to the shank and two rings with bridges of metallic strain gauges measure the net force to which the paw is submitted. If the isotonic pattern is to be studied, weights (Fig. 3, no. 14) are attached to cords over pulleys (Fig. 3, no. 15), the foot can freely turn around the

ankle, and its movements are measured with the potentiometric sensor. All the input and output signals can be checked by viewing on an oscilloscope and can be recorded.

RESULTS WITH ISOMETRIC CONTRACTIONS

In order to determine whether a model of muscle associated with an optimal nervous control is possible, we had to determine the influence of the different stimulating parameters on the contraction of the muscle *in situ* with both isometric and isotonic conditions. The present paper reports only isometric experiments.

Experiments with Isometric Contraction

The location of the foot with regard to the shank is fixed so as to keep the length of the muscles constant. One of the muscles is stimulated using impulses of different frequency, amplitude, and width.

1. Influence of The Pulse Frequency

With a pulse amplitude strong enough to affect the muscle (and a fixed pulse width) a force is developed which depends on the frequency. For the very low frequencies, the muscle responds in a one-to-one relationship, but the average value of the force developed rises with frequency. At a pulse repetition rate of about 20-25 Hz, an "integrated" response appears. That is to say, the muscle has no time to slacken between impulses, the inertia of the limb segment exerts a smoothing effect, and a continuous force is obtained (Fig. 5, force is expressed in Kgf, 0.1 Kgf = 1 Newton). Beyond 25 Hz, the force seems to reach saturation and it does not increase significantly even at 50 and 60 Hz.

These results with varying frequency indicate that the static force developed by the muscle cannot be controlled in a useful way by variation of the stimulating frequency. Indeed, in the zone where force rises with frequency, we obtain a one-to-one response from a single pair of electrodes, and in the zone where the force seems to be continuous, it depends only slightly on frequency.

2. Influence of Pulse Amplitude

With a stimulating frequency between 30 and 60 Hz and a fixed pulse width, the force generated by the muscle is a function of pulse amplitude, as shown in Figure 6. As the amplitude rises, the force developed quickly increases from threshold and reaches saturation. Increasing the amplitude still further causes a decrease of the net force due to the parasitic excitation by diffusion of the antagonistic muscle. In the case shown, the useful range is 200-300 mV.

FIGURE 5.—Recordings of the tensile force developed by the triceps surae. Tibial nerve excitation: fixed amplitude; fixed pulse width (150 μs); frequency: (1) 5 Hz, (2) 10 Hz, (3) 13 Hz, (4) 20 Hz, (5) 32 Hz, (6) 42 Hz, (7) 50 Hz. Tensile force measured by pure crystal silicon transducer or MOS (metal oxide semiconductor) transducer.

These results show the existence of an upper limit for the stimulating amplitude, a threshold which must not be exceeded so as not to work in the saturation zone. There is typically a long linear portion.
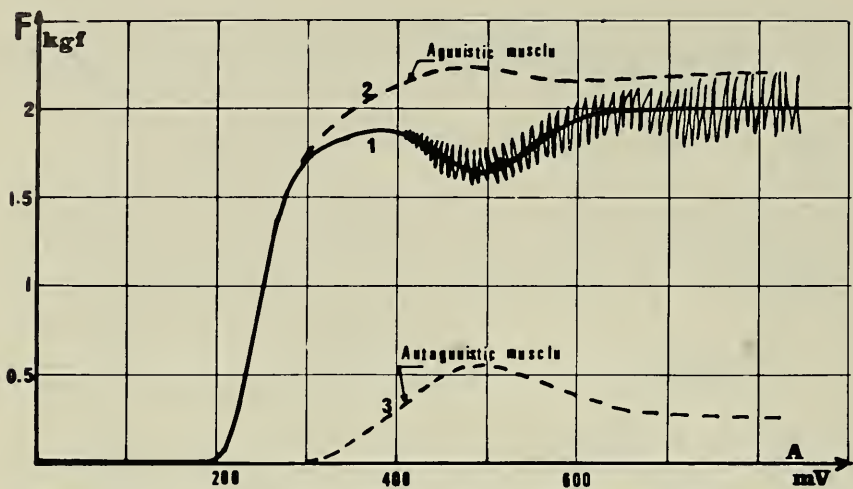
FIGURE 6.— Variation of the force developed with the stimulating amplitude: 1. Measured force—excitation of the tibial nerve, 2. actual force developed by the tibial, and 3. force developed by the triceps (consequence of the diffusion of the stimulating signal when amplitude becomes too high). On the Y axis is the signal given by the metallic gauges bridge. The signal is directly proportional to the force developed.
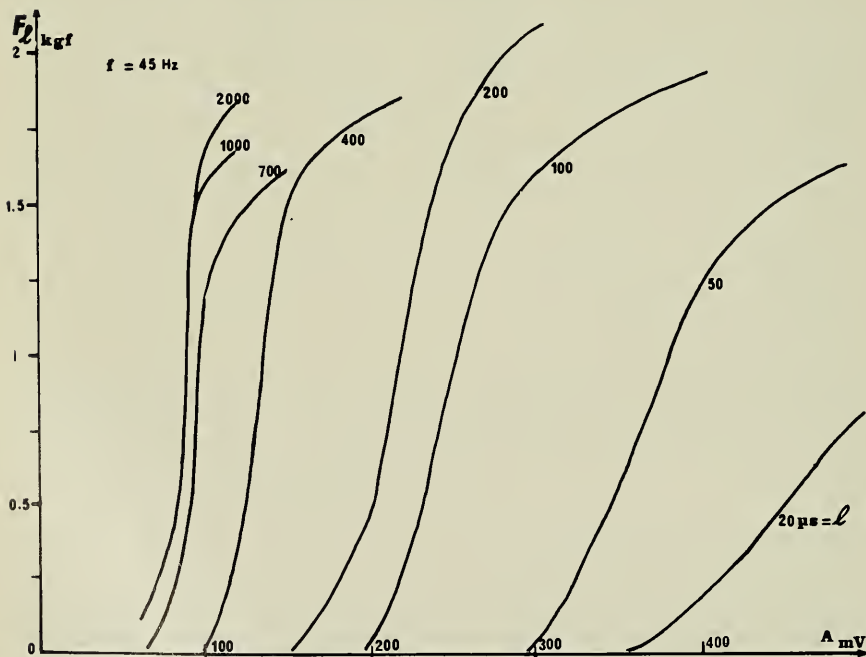
FIGURE 7.— Force developed by the tibial as a function of stimulating amplitude for fixed widths.

3. Influence of Pulse Width

Now we must determine whether both previous limits of useful force depend on the pulse width. The force-amplitude curve is repeated for a great variety of conditions of frequency and width (e.g., Fig. 7). We can then draw (Fig. 8 and 9), the zones where stimulation may be regarded as adequate for the dog's anterior tibialis.
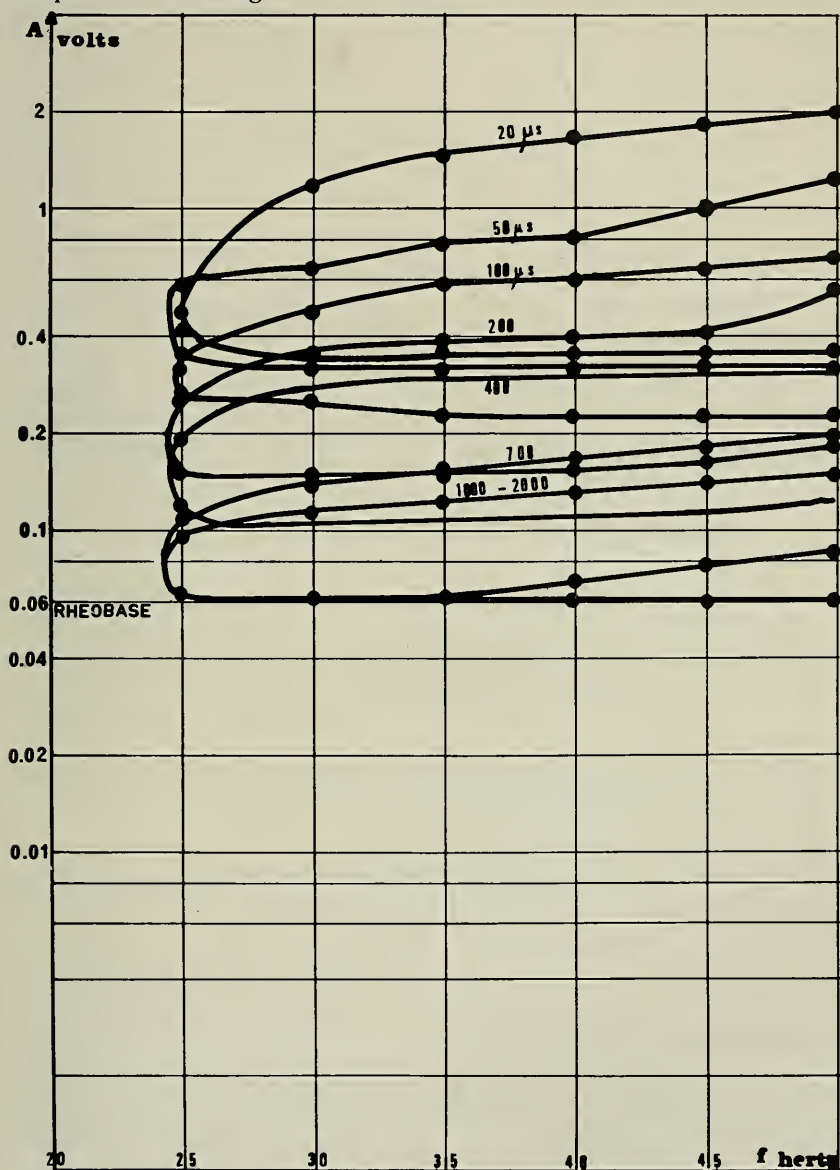
FIGURE 8.—Zones of acceptable stimulation of the muscular nerve in the amplitude - frequency impulses width space.
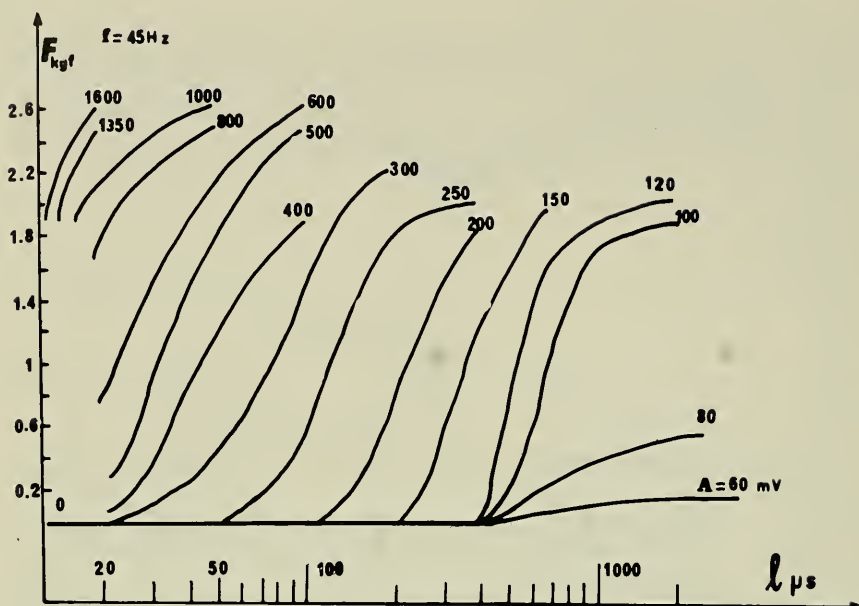
FIGURE 9.—Force developed by the tibialis as a function of the width of the stimulating impulses, for fixed amplitudes.

The study of these curves indicates that:

1. The zones are all larger with small pulse width.
2. The maximum force is obtained for an amplitude which varies inversely with width.
3. With pulses less than a millisecond in width, force seems to be independent of the width.
4. The rheobase is approximately 60 mV.

The chronaxy is about 400 μs. These values for striated muscle are in agreement with those provided by various authors (13).

Search for Isometric Muscle Control

Let us sum up in a mathematical way the constraints and laws to which the control of the muscular contraction is imposed. Let f, A, l, be the frequency, the amplitude, and the width of the stimulating impulses. F represents the force developed by the stimulated limb. Then with a constant frequency, f, lying between 30 Hz and 60 Hz:

a. — for l between 0.0 and 1.0 ms.

A min. = $g_1 (l)$

A max. = $g_2 (l)$

— for l greater than 1.0 ms.

A min. = constant

A max. = constant

b. — $F_l = h_1 (A)$, A min. $\leq A \leq A$ max.   [1]

$F_A = h_2 (1)$, A min. $\leq A \leq A$ max.   [2]

It is now interesting to explain as much as possible the form of the equations [1] and [2]. Figures 7 and 9 show the variations of the force for equal-width and equal-amplitude pulses. The general aspect is the same as Figure 6; as far as an important percentage of the maximum force allowable is concerned, it is possible to linearize this force. Such a linearization will make the solution of the control problem easier.

To bring the force developed by a muscle to a certain level, there are a great number of possible combinations of the control variables inside the zones previously defined. The evolution of the parameters is determined according to the following criteria: search for a minimization of energy provided to the nerve, search for the development of the maximum force, and search for a minimization of the time taken for the force to be established. Compromises may be needed to allow reasonable forces to be sustained for useful periods without fatigue.

PART II. — OPEN LOOP CONTROL OF MUSCULAR CONTRACTION

INTRODUCTION

The first part of this work defined the usable space for the stimulating parameters (frequency, width, and amplitude of rectangular voltage pulses) of the internal and external popliteal sciatic nerves which control the contraction of the anterior tibial and triceps surae muscles of the dog. Using amplitude as a parameter, however, does not give repeatable results because the stimulation depends on the particular electrodes used. The electric charge[b] sent to the nerve is a better parameter because

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b The charge (q) is the integral of the current: $q = \int i \bullet dt$.

it is independent of the electrodes and characteristic of the degree of muscle contraction. In practice, it is easier to measure the applied voltages and durations than to measure charge, and the results in both cases are similar if the real part of the impedance Z between the two electrodes remains constant.

The results given here have been obtained with new improved electrodes, compared to those used in Part I. The silicon has been replaced by a very flexible material (Rhodergon). The nerve-electrode junction has been improved, so there is less risk of damage to the nerve, which could become somewhat swollen during the experiments. The real part of the nerve-electrode impedance decreases significantly causing the excitation thresholds to decrease with it.

With these new experimental conditions, it is possible to synthesize stimulation signals, so that the force developed (isometric mode) or joint rotation (isometric mode) can be controlled in the desired manner.

THE CONTROL FORCE IN ISOMETRIC MODE

As in the previous paper (Part I), the force developed as a function of amplitude and pulse width is once more shown here. In Figure 10, the
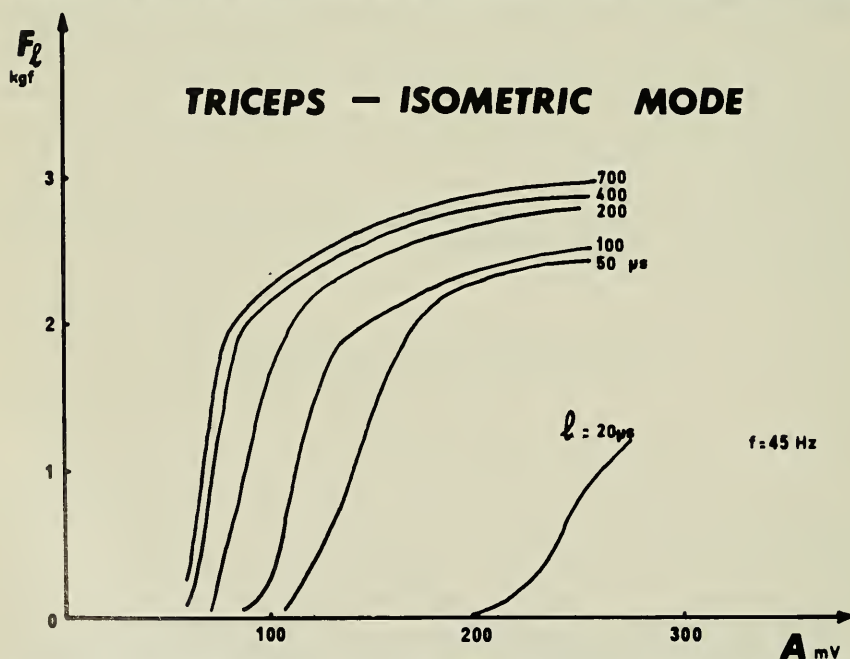
FIGURE 10.—Force developed by triceps in relation to stimulating amplitude for fixed widths.

independent variable is width; in Figure 11, it is amplitude. These curves were obtained using the new electrodes and the triceps of the dog. The frequency was held constant at 45 Hz.

TRICEPS — ISOMETRIC MODE
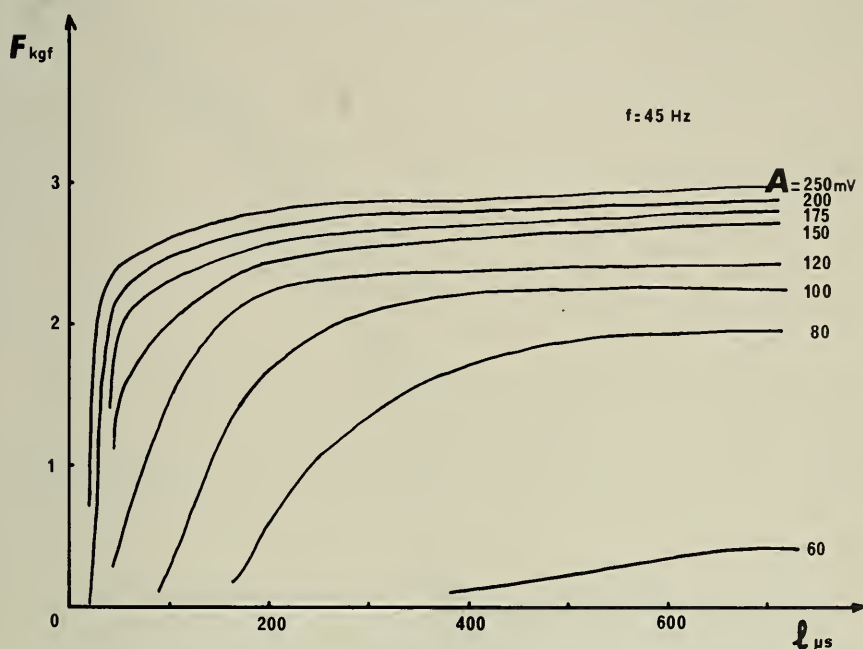
FIGURE 11.— Force developed by triceps as function of the width of stimulating impulses, for fixed amplitudes.

To bring the developed force by the muscle from zero to any desired value, it is possible to use variations of width, amplitude, or any other combination of these two parameters. It was seen that keeping frequency at a fixed point is more interesting (see Part I). But what value should be used in the 25-60 Hz range? To help in making this choice, three criteria that influence the design of muscle stimulators have been investigated.

A. Minimization of Energy

Minimizing the energy delivered to the nerve is important both for maintaining the nerve in good condition, and for miniaturizing and possibly implanting the stimulator. The equation for the power (or energy per unit time) is:

$$P = \frac{f \cdot l \cdot A^2}{Re(Z)}$$

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where f is the pulse frequency, l the pulse length, A the amplitude and Re (Z) the real part of the nerve impedance. The force as a function of the power of the stimulating signal is shown in Figure 12.
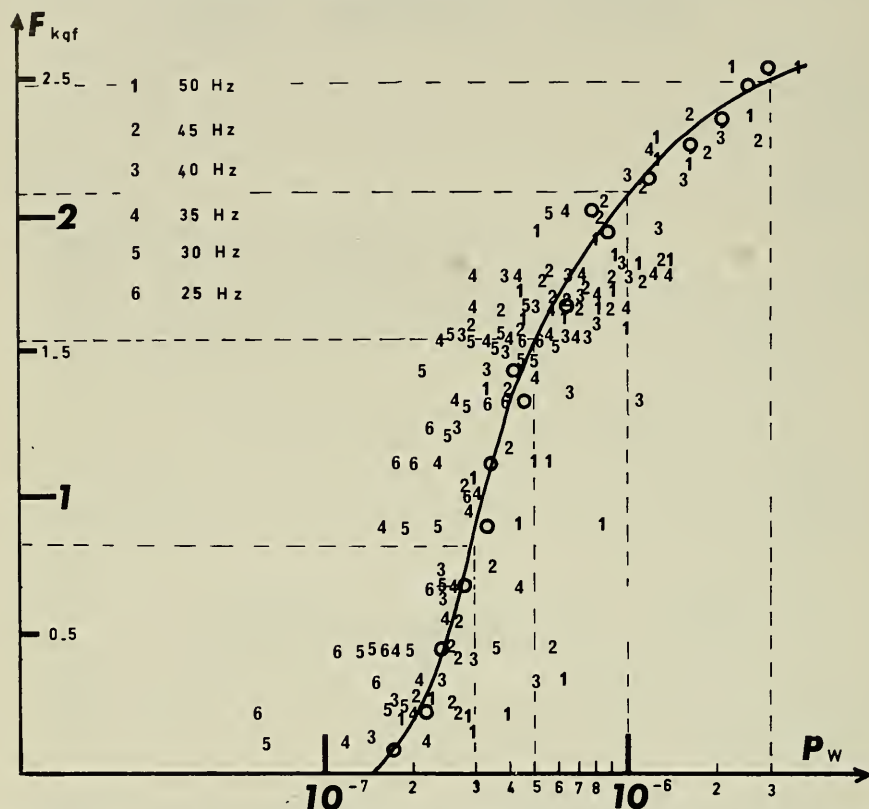
FIGURE 12.—Force developed for each frequency in relation to the power of stimulating signal.

Despite a fairly large dispersion of the representative points, a curve is obtained by averaging all the values at a given force but a varied frequency. Figure 13 shows the averaged results, which exhibit both a saturation and threshold. Although numerous mathematical expressions can be used to approximate this curve, we have chosen very simple ones. Segment AB of the curve is almost a straight line, which is expressed by the following linear equation:

$$F \text{ kgf} = 5.31 \cdot 10^6 \, P_w - 0.85$$

$$(1.6 \cdot 10^{-7} < P_w < 4 \cdot 10^{-7})$$
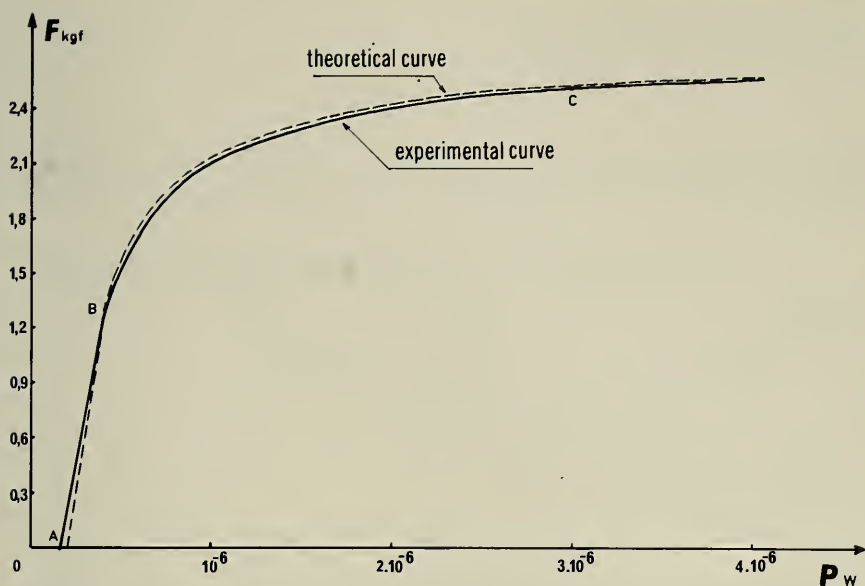
FIGURE 13.—Means of force versus power of stimulating signal dashed line: Fkgf = 2,7 – (0,57. 10⁻⁶) /Pw.

Segment BC is expressed by the following hyperbola:

$$F \text{ kgf} = 2.70 - \frac{0.57 \cdot 10^{-6}}{P_w}$$

$$(P_w \geqslant 3 \cdot 10^{-7})$$

In order to find a pulse width which represents the minimum power consumption, the ratio (F/P) is drawn as a function of P for each pulse width (Fig. 14). The results show that to minimize the energy consumption, there is no preferential width. (Actually, the integral of the ratio F/P over all P values must be considered). The same calculation is required for each frequency. The results are relatively identical and in terms of energy spent inside the selected frequency range, no pulse frequency appears to be preferential.

The criterion of energy minimization does not give the necessary elements to fix either of the parameters. It is possible to control the force from zero up to its maximum value while continuously minimizing the power (e.g., $A^2 l$). In Figure 15, lines of equal force are represented in logarithmic coordinates (log A and log l). To move on this plane following the minimum energy rule, the displacement from one curve to

another should stay on the tangent point of the curve F = constant with the parallel to the straight line:

$$\log l + 2 \log A = 0$$

This line is shown dashed in the lower left area of Figure 15 and a series of parallel lines are shown tangent to the curves for constant force.
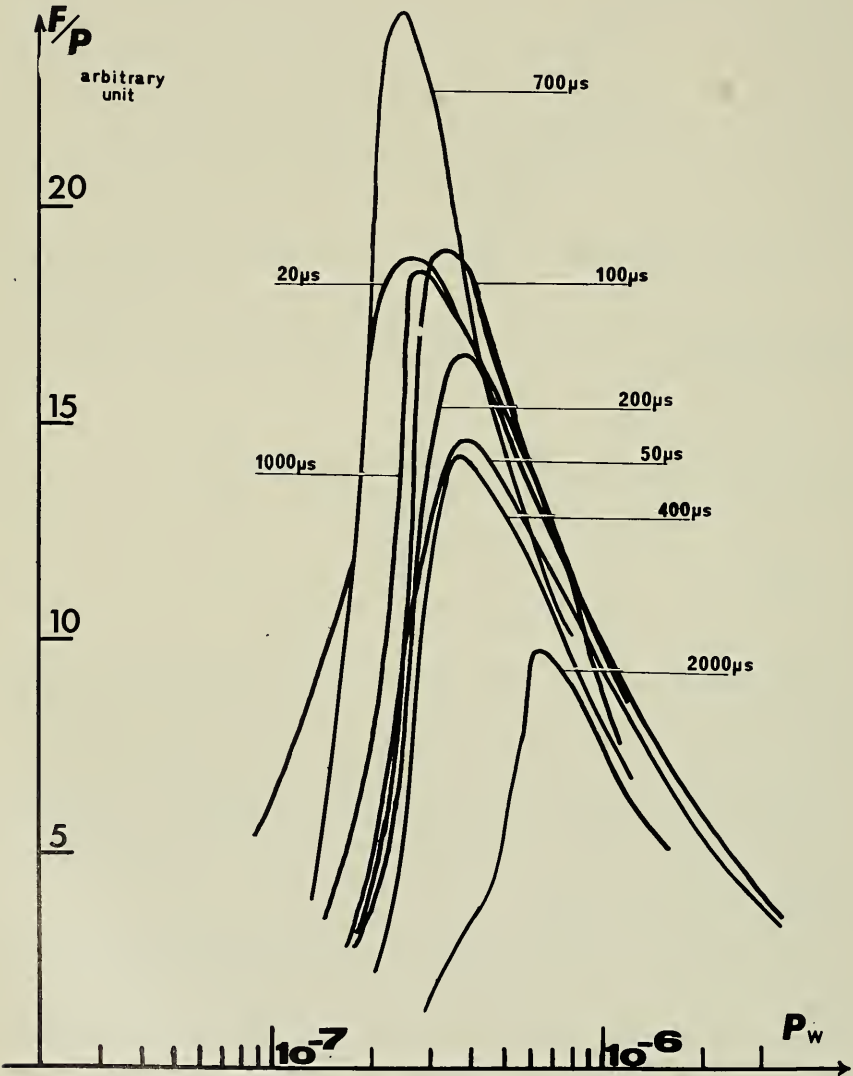
FIGURE 14.—F/P output as function of power of each impulse width.
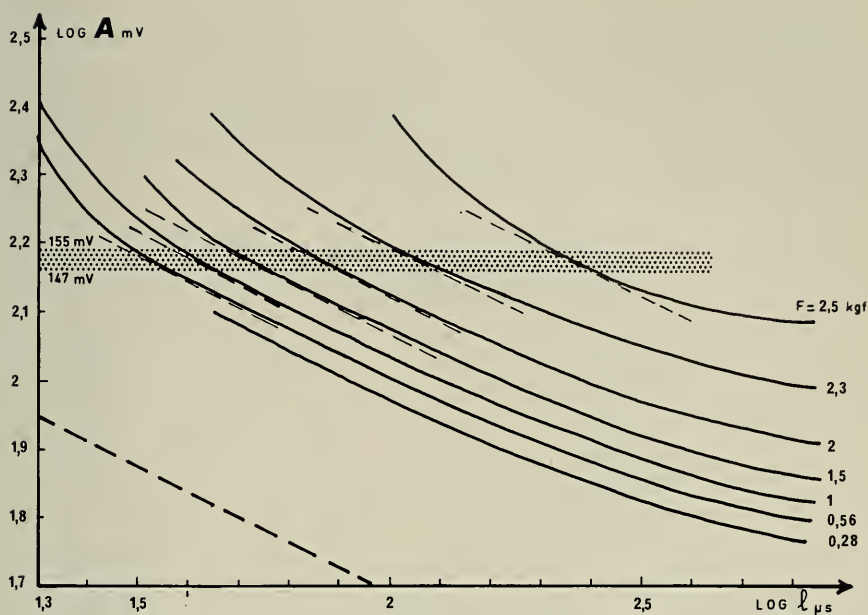
FIGURE 15.—Search for a control of triceps by minimization of stimulating power—A≈150 mV lies between 30 and 300 μs.

It is then found that by keeping the amplitude fixed (about 150 mV) and by increasing the pulse width by about 30 μs, it is possible to control the muscular force while simultaneously minimizing the consumption of energy. This procedure for optimal control of the muscular contraction is very easy to implement since it leaves two parameters fixed and requires only one parameter to change. It is shown as the shaded area corresponding to the zones where tangents to the curves of constant force are parallel (approximately) to the desired line for maximum power (this zone is at 147 − 155 mV).

B. Minimization of Response Time

The transient response of the muscle to a step application of the stimulating signal is characterized by the time separating the application of the stimulus and the appearance of the maximum force. This interval defines the "response time" of the muscle. If useful muscle control is wanted, the response time must not exceed a few tenths of a second. Obtaining short response time then is more important than minimizing the power.

In Figures 16, 17, and 18 the response time is given as a function of the developed force respectively for fixed frequency, fixed width, and fixed

amplitude. To obtain a certain value of force at a given frequency (Fig. 16) or given amplitude (Fig. 18) two response modes are possible: one exhibiting quick response (0.1 to 0.2 sec.), the other a slow response (up to 10 sec. or more). Figure 17 demonstrates this point by showing that slow responses are the result of short pulse widths and that fast responses are due to long pulse widths.
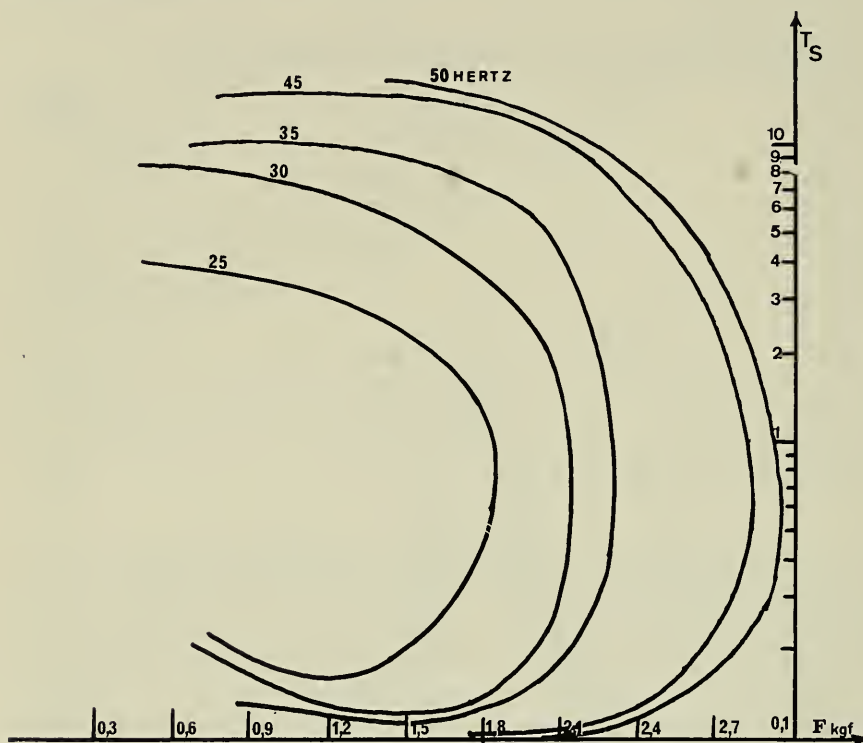
FIGURE 16.—Response time versus force with fixed frequency.

To reduce the response time it is necessary to work with large widths. This is the opposite of the previous criterion (energy minimization) which calls for a fixed amplitude and increasing width. To obtain reasonably quick response it is necessary to fix the width and to control the amplitude.

C. Criterion of the Maxima

It is possible to limit the problem still further by imposing the following restriction: that with the system of stimulation, the maximum muscular force desired can be obtained. As we have shown, the maximum force developed by a muscle varies with the stimulating parameters (see Fig. 7,
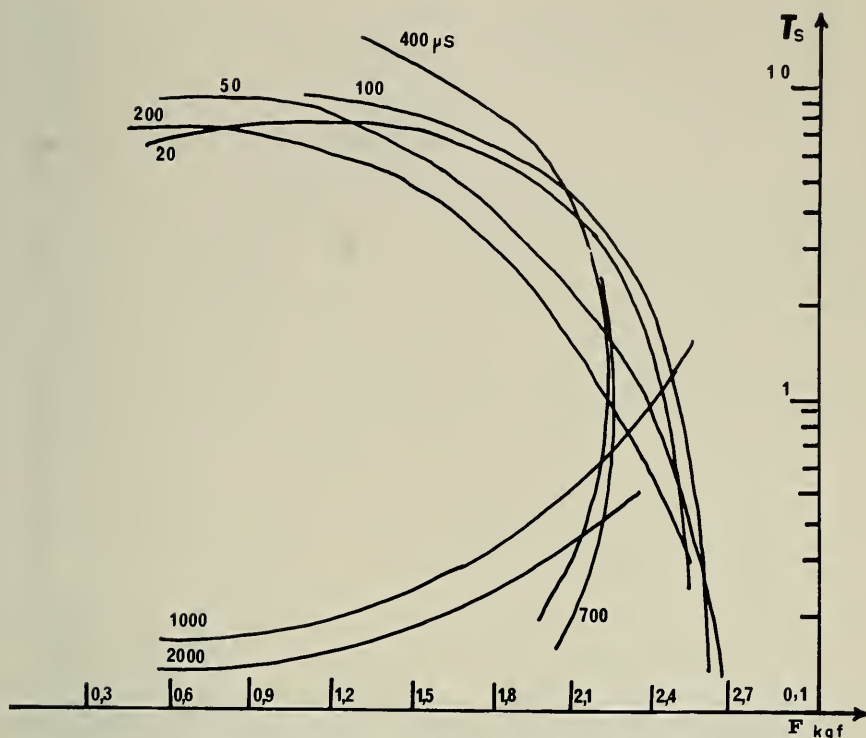
FIGURE 17.—Response time versus force with fixed impulse width.

8, and 9 of Part I). It was found that F max. increases slightly with the frequency but decreases as the pulse width increases.

The greatest muscle force obtained in all the experiments was with 20 μs pulses at a frequency of 50 Hz. This would fix the frequency and pulse width, and muscle control could be carried out by varying the amplitude. In practice it may not be necessary to develop muscle force to its utmost limits because muscle fatigue may develop more quickly than with another choice of excitation. Also, there is not a large difference between the maximum force developed with different types of stimulation, as the maxima in all cases are at least 75 percent of the largest value force obtained.

D. Summary

Let us summarize the results obtained during these experiments with isometric contractions:

a. The force developed by the muscle is almost independent of the excitation frequency provided that it is between 25 and 60 Hz. Operating in this field it is possible to ensure a reasonable muscular contraction.
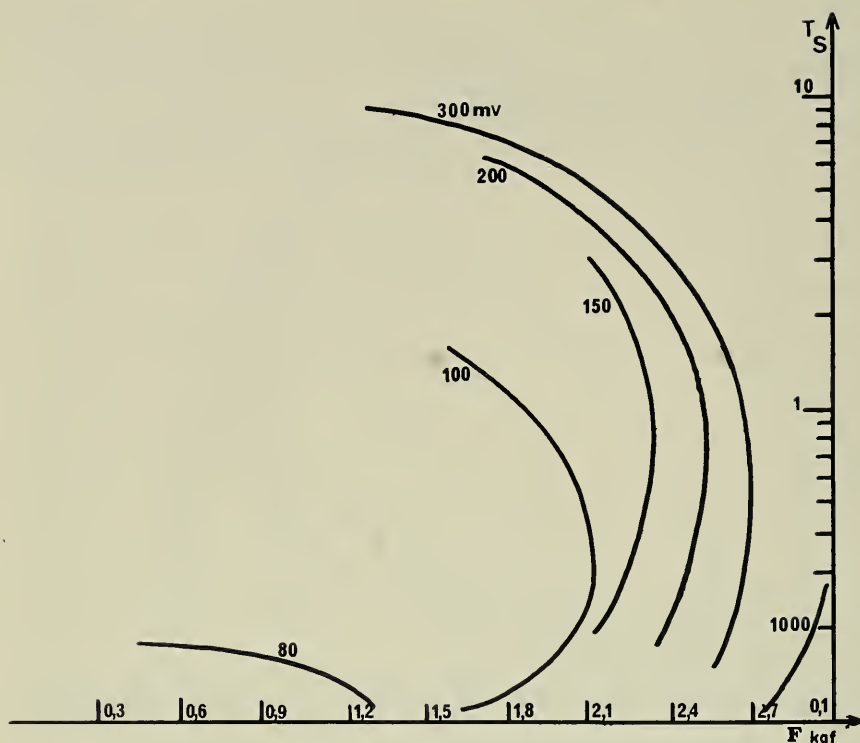
FIGURE 18.—Response time as function of force with fixed amplitude.

On the other hand, it depends strongly on the pulse amplitude and width.

b. Some intuitively reasonable criteria were applied in an attempt to limit the variables. It was found that criteria were not compatible with one another and for practical application the criterion of minimum response time was chosen to obtain a control model.

c. The experiments were carried on the tibialis anterior and triceps of 12 dogs. Except for physiological differences, the results were qualitatively identical in all the experiments. This uniformity will enable the control of the triceps or tibial contraction independently of the subject with the same stimulator. Individual differences may be compensated for by changing the amplitude or pulse width, both of which are easily adjustable.

CONTROL OF ISOTONIC CONTRACTION

In this case, the four parameters concerned are:
1. The angle of rotation of the joint.

2. The force developed by the paw in a given position.
3. The stiffness (or its reciprocal, the compliance).
4. The velocity of displacement or of rotation of the joint.

A. Summary of Experimental Results

As a function of the various stimulation parameters, output parameters were recorded and graphed. Figures 19 and 20 show the variation of the angle of rotation of the joint, caused by stimulating the triceps and tibialis anterior as a function of pulse width (for a frequency of 45 Hz) with several values of amplitude. Note particularly that the greater the amplitude, the more the variation of the angle with the pulse width. If the stimulating amplitude is inadequate, the maximum rotation may not be obtained, no matter what the width may be. The same type of reduction occurred in the isometric experiments.
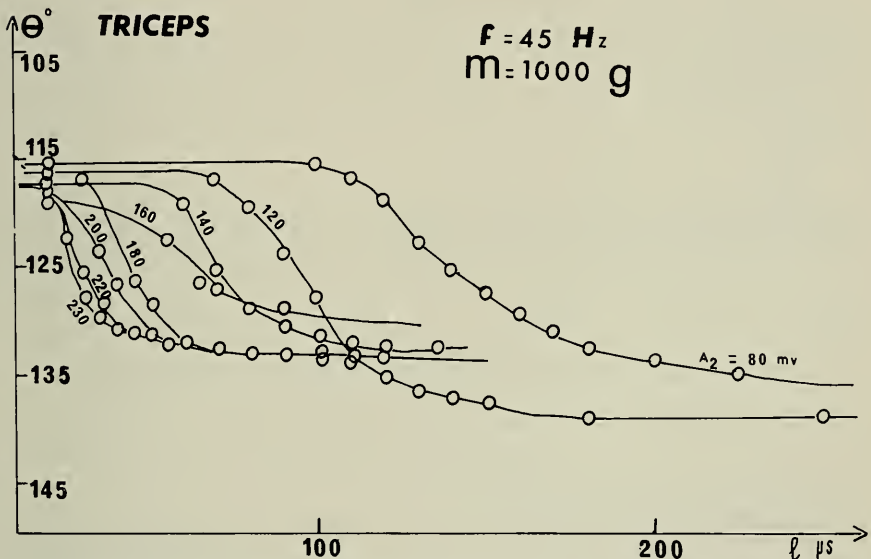
FIGURE 19.—Rotation angle of paw as function of triceps stimulating impulse width with fixed amplitude. The force to be pulled is 1 kgf.

As a general rule, the displacement of the foot needs the excitation of only one muscle; tibial is for flexion, triceps for extension. The unexcited muscle behaves passively but can oppose the rotation of the joint if its zone of elasticity (passive stretch) is situated too far from the zone of its length at rest. To obtain a given stiffness at the foot when it is placed at a given angle of rotation, both muscles must be stimulated. An increase of contraction of one must be compensated for by an increase of the contraction of the other; the foot does not move but the limb stiffens.

By acting manually on the output of the stimulator, the foot was brought to a predetermined position, in a time determined in advance and resisting a predetermined force (within certain limits), thus demonstrating that it is possible to completely control the paw in the open loop situation.
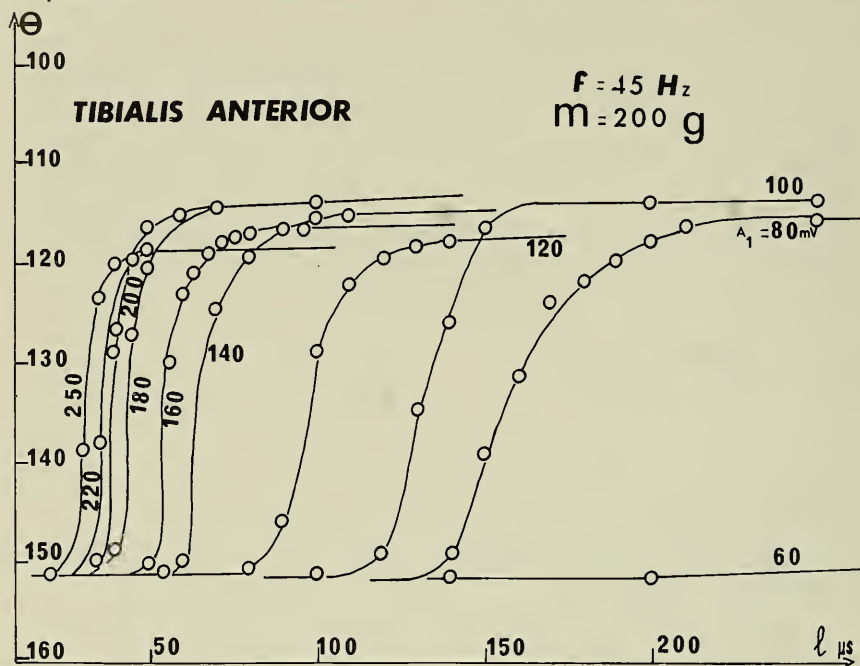
FIGURE 20.—Same experiment with tibialis, the force to be pulled being 200 g.

B. Modeling of Articular System

The external control of muscular contraction, and consequently, the joint rotation has been experimentally studied. It is possible to make a model of the foot which is operated by nervous stimulation of the tibial and triceps muscles. Figure 21 shows this model with a position control. Excited by the stimulator S_1, the muscle M_1 (for instance tibial) develops a force F_1 which is a function of its length D_1 and of the level of stimulation (l_1, A_1) of its nerve:

$$F_1 = F_1 \ (D_1 \ [l_1 \ , \ A_1])$$ [1]

Likewise

$$F_2 = F_2 \qquad (D_2 \ [l_2 \ , \ A_2])$$ [2]
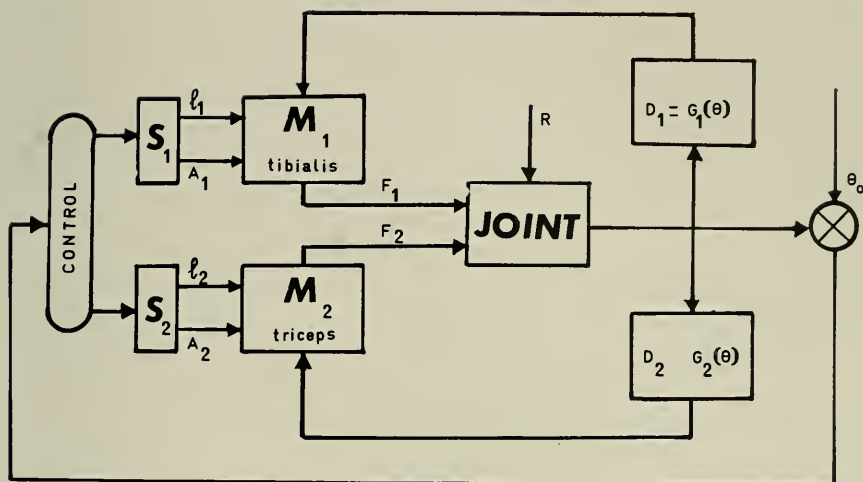
FIGURE 21.—Mechanical pattern of paw for position control: S_1—stimulation (A_1—impulses amplitude); l_1—width; M_1—flexor (tibialis); S_2—stimulator; M_2—extensor (triceps); F_1, F_2, forces developed by muscles on joint; R—exterior force; and θ—angular position of paw.

Both forces are exerted on the joint, as well as the exterior force R, so that the angle θ is a function of all three forces (and their respective lever arms).

$$\theta = \theta \, (F_1 \, , F_2 \, , R)$$

A mechanical relation binds D_1 , D_2 , and θ. To reach an angle θ_0 the difference $(\theta_0 - \theta)$ drives the stimulation.

So the mechanical function of the system (Fig. 22) is described by the following equations:

α. the force-length stimulation relations [1] and [2]

β. the geometric relations between the lengths of the two muscles:

$$g \, (D_1 \, , \, D_2 \,) = 0$$

[3]

γ) the equation of the movement:

$$I \, d\tfrac{1}{4} \, \theta \, / \, dt^2 \, = M$$

[4]

I : Moment of inertia of paw around joint axis

M : Moment of forces F_1 and F_2 and R in relation to joint axis.

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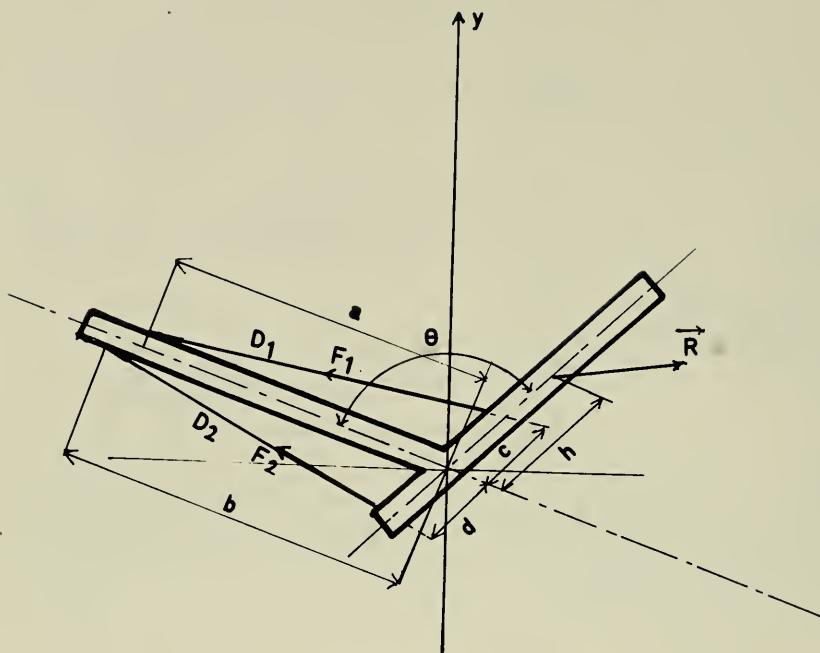
FIGURE 22.—Diagram representing the joint as it can be geometrically and mechanically described: D_1—tibial length; D_2—triceps length; F_1—force developed by the tibial; F_2—force developed by the triceps; R—exterior force; θ—angle of rotation of the foot; n—distance between the application point of R and the center of rotation of the ankle; a—distance between the insertion point of the tibial and the axis of rotation; b—distance between the insertion point of the triceps on the tibia and the axis of rotation; c—distance between the application point of F_1 and the axis of rotation; and d—distance between the application point of F_2 and the axis of rotation. The joint is supposed to be perfectly rotatable and free from friction.

With a knowledge of the lever arms, the paw mass, and the external force R, and measuring at each time F_1, F_2, and θ, it is possible to predict the operation of the system.

THE PROBLEM OF FATIGUE

Fatigue is the most important factor which can change the control

characteristic of the muscle. However, if the muscle is called on to generate a long sustained force, its power decreases progressively.

The time between the beginning of the stimulation and the appearance of the fatigue is a function of the force developed by the muscle (no fatigue under F max./5.0 (14)). It has been found that there is no fatigue during periods of up to 20 minutes, providing that the force developed by the triceps is about 0.5 Kgf ($\simeq$ F max./5.5). Therefore, the maximum force behavior versus time has been studied.

Figure 23 a shows a diagram of an experimental setup to test the triceps. The mass m is adjusted so that whatever the level of triceps stimulation the mobile part of the paw (OB) is not blocked. The levels of stimulation are adjusted to the minimum value consistent with the greatest value of angle AOB = θ.

θ is recorded versus time which is qualitatively the same thing as measuring the triceps maximum force. (Slow variations of static equilibrium are measured.)

Experimental results are shown in Figure 23 a. Figure 23 b shows a typical response.

a. Force F max. (equivalent to $\theta = \theta$ max.) can be seemingly held constant during about $t_1 = 20$ seconds.

b. For $t > t_1$ this force decreases regularly. In each case, it can be estimated up to 50 percent of the maximum force after 5 to 8 minutes.

c. The recuperation time, that is the amount of rest necessary for the muscle to obtain maximum force in two successive experiments, is about 15 minutes.

Figure 23 c shows the reduction in muscle after the arterial and venous muscle circulation was stopped by clamping the blood vessels (p = clamping point).

When the nerve is clamped however, between the muscle and stimulation zone (Figure 23 d, n = clamping point), the force (or the angle) decreases more rapidly than in Figure 23 a, but follows the same type of curve.

The muscle developed force control, described in the previous paragraphs, can only be carried out if the maximum force is maintained for less than 20 seconds. This means that in practice, the research of the minimum developed forces suited to the desired result must be continually effected.
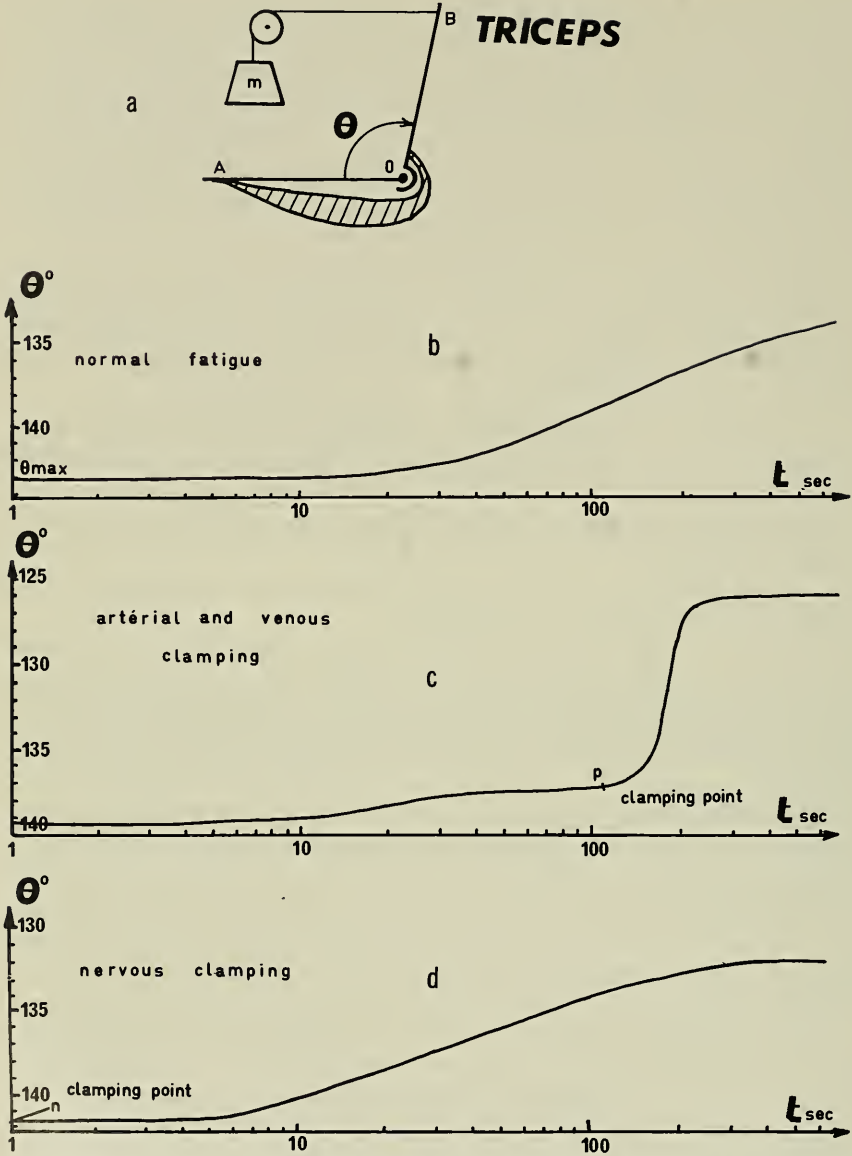
FIGURE 23.—a. Experimental setting for fatigue studies; b. θ versus time for maximal contractions; c. θ versus time for maximal contractions with arterial and venous clamping (clamping instant is shown); and d. θ versus time for maximal contractions with nervous clamping.

CONCLUSION

The experimental results summarized in this paper allow a better understanding of the joint motion control problem.

A given force can be developed (under isometric conditions) or the limb placed in a desired position (under isotonic conditions) by means of a simple electronic device.

The experiments described in this study lead to the following conclusions:

1. From a qualitative point of view, the problem of muscular control by external stimulation without fatigue seems to be solvable. Fatigue, resulting from the maintenance of a given force for an extended period of time, changes the relation between the stimulus and the developed force, and reduces the maximum amplitude of the developed force.

2. From a quantitative point of view, the parameters of the external nervous stimulation and their limits were determined for several experimental dogs.

3. With these results, adequate experimental stimulators and sensors were built which will allow more precise studies to be carried out.

The next logical phase of this work is to bring under control, by means of external feedback, either the amplitude of the force developed by skeletal lever, or its position and velocity. Thus, it is necessary to establish a mathematical model of the system formed by two stimulators controlling the agonist and antagonist muscles at a particular joint. This model, simulated on a hybrid calculator, will then permit the determination of a closed loop control system which will deliver a stimulating signal to the muscle to achieve the forces and positions commanded by a reference signal (2).

A study is being carried out on the form and materials required to chronically implant a stimulator. These developments will be reported in a later publication. Therefore, a simple control system without an external orthosis can be foreseen for the movement of a single joint even though the nervous system is not able to utilize the sensations of displacement or force. In later stages the sequential control of joints would offer the beginning of a solution to certain rehabilitation problems in paraplegic cases.

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ACCELERATION OF BONE HEALING BY ELECTRICAL STIMULATION

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Stimulation of bone and soft tissue healing by means of artificial application of electrical energy is a research frontier offering promise of major progress in orthopedic and rehabilitation treatment. Advances in this field could give the clinician a measure of direct control over the processes of healing.

Attempts to stimulate bone healing with electrical energy are based on certain observations concerning inherent electrical activity in bone. Many investigators have shown that bone generates an electrical potential in response to mechanical stress, and that application of specific types of small electric currents can stimulate bone formation; under appropriate conditions bone will be formed around a cathode extending into the medullary canal.

Although limited clinical studies are in progress in several centers, development of electrical stimulation of bone as a treatment modality is in its infancy; the problem remains to convert a laboratory phenomenon into a practical tool to produce clinically significant amounts of new bone.

The purpose of this project is to develop techniques by which electric currents may be utilized to stimulate deposition of a significant amount of new bone in nonunions and large defects in bone, clinical problems of special interest to the Veterans Administration. Before this goal can be achieved, detailed laboratory studies are necessary to develop appropriate electrical parameters and to observe effects on healing of potential and established nonunions. The first year of the project was spent in standardizing a suitable animal model for this application, and in developing the necessary stimulator and electrode implants in association with Avery Laboratories.

The experimental model is a bone defect created surgically in mature dogs by excising a segment of distal ulna extraperiosteally; it results in a permanent defect in the ulna. To apply electrical currents to this defect, a special array of platinum electrodes on a fixed bracket was devised. Leads are run subcutaneously to the axillary region where a self-contained battery-powered stimulating unit is implanted.

Several stimulation modes are being tested, including continuous d.c. and various configurations of pulsed current. In this series, each animal serves as its own control. A precisely similar procedure is carried out on the opposite limb, but electrode leads are connected to a dummy stimulator with high resistance representing the active unit. As the radius is left intact, the animals resume normal activities almost immediately.

Effects in stimulated and control defects in each dog are compared by X-ray, histological, and radioactive tracer techniques. This experimental model offers an excellent opportunity to answer many vital questions concerning bone stimulation which must be clarified before one can hope to achieve success in clinical applications.

Results in the first year were limited due to a variety of mechanical and electronic problems with the commercially constructed electrodes and stimulators. For the second year, the entire implant system was redesigned: no significant technical problems are being encountered, and promising results are being seen.

In another area, a major success was achieved the first year of this project. In selecting a mode of electrical stimulation, it is desirable to know the nature of the normal pattern of stress generated electrical potentials in bone so that they may be duplicated. While many measurements of these potentials in bone have been made, the true dynamic pattern in vivo has never been delineated. To answer this question, a method was developed to study the potentials generated in long bones in animals during normal walking and to correlate the electrical activity directly with mechanical strain.

Utilizing these new techniques, electric potentials and mechanical strain were recorded simultaneously directly from the bone during normal walking of the dog 10 days postoperatively. Excellent correlation between mechanical strain and electrical activity was noted (Fig. 1 and 2). Additional experiments involving controlled manual bending of the leg demonstrated a pattern of electrical activity similar to that known to be generated by moist bone in vitro (Fig. 3). These manual tests confirmed that the normal result of strain caused by weight-bearing is not potentials of equal magnitude and opposite polarity; rather, the potentials are unequal, suggesting that net unidirectional current flow exists. This correlates with observations that pulsed unidirectional currents are most efficient in promoting bone formation. After further experiments are completed, this type of data will help to determine the most effective specifications for electrical stimulation in terms of frequency, pulse duration, and waveform.

It is hoped that this project will lead to significant advances in the rehabilitation of patients with bone nonunions or large defects in bone.
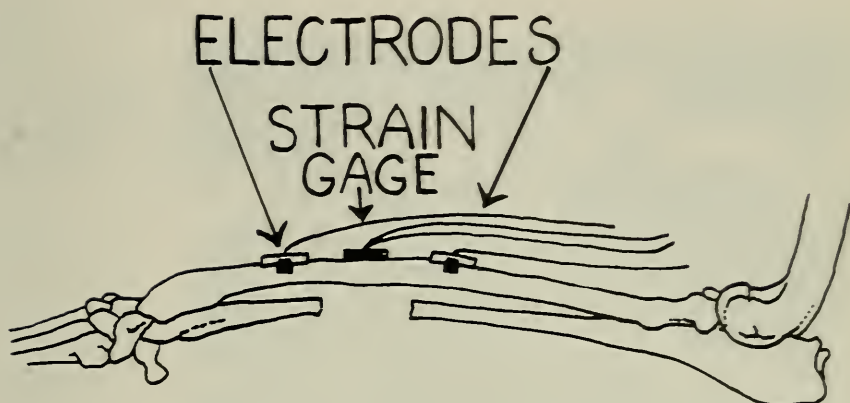
FIGURE 1.—Diagram of electrode and strain gage configuration utilized in a dog for recording of electric potentials and mechanical strain from bone during walking. The defect in the ulna facilitates recording by increasing strain levels in the ulna.
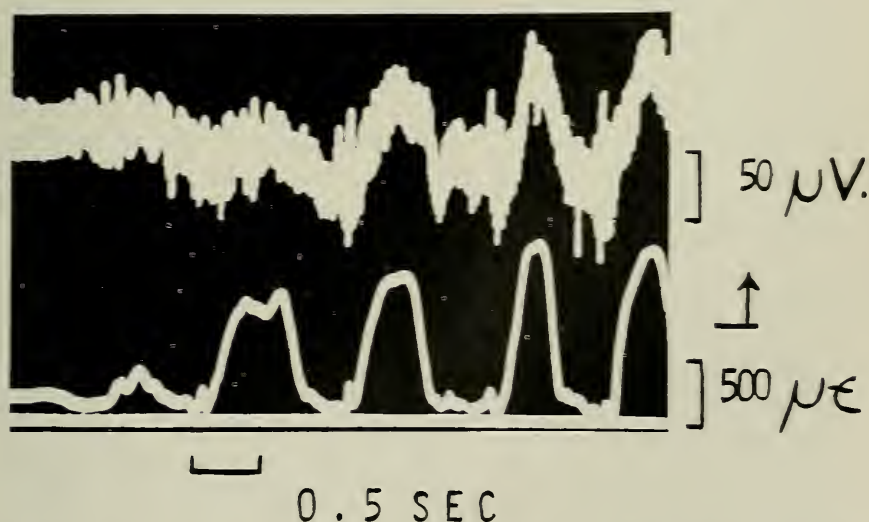
FIGURE 2.—Recording of electromechanical events during walking from preparation diagramed in Figure 1. Electric potentials (top) correlate with mechanical strain (bottom).
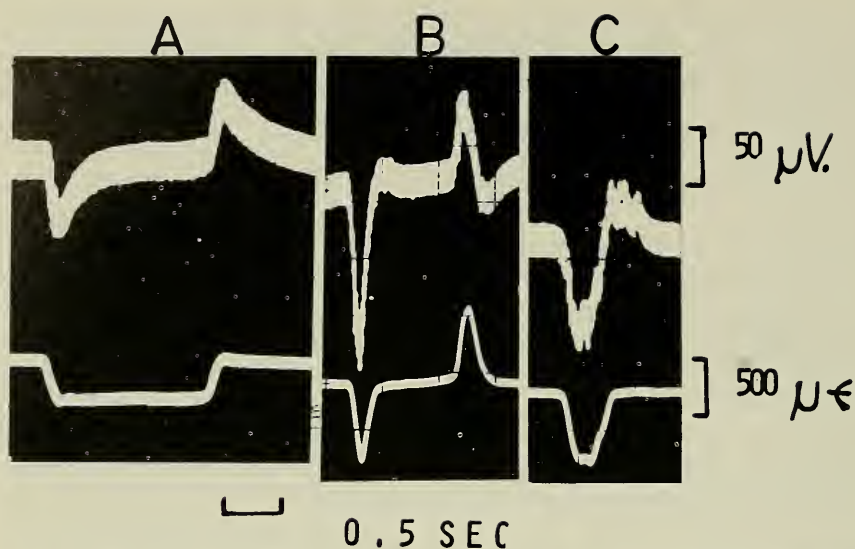
FIGURE 3.—Recording of electromechanical events from canine radius during controlled manual bending of the forelimb: (top) electric potentials. (bottom) mechanical strain. A. symmetrical positive and negative voltage waveforms developed by rapid onset, maintenance, and release of deformation. B. Reversal of polarity with reversal of strain. C. Asymmetrical voltage waveform developed in response to strain input simulating weight-bearing.

Orthotics, Spinal Cord Injury, and Other Severe Disabilities

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Moderator

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On a purely personal note, may I suggest as we turn from the prosthetics side to orthotics that this area has a historic interest for me. After I had poliomyelitis 50 years ago, in July 1924, I became involved a great deal in the era of the wooden wheelchair, crutches, canes, full-length leg braces, and then short ones. I still use orthopedic shoes and two canes.

The number of patients requiring orthotic and other aids is perhaps 10 times as great as the number of amputees. Though there is a good deal of interrelationship among these various areas of orthotics, spinal cord injury, and aids for other severe disabilities, there is also great diversity. We have not entirely postponed this area, though it received a lesser share of the available limited budgets. There are much more diffuse, much more difficult problems in orthotics than in limb prosthetics. There is a much larger diversity of indications, which creates more problems in selecting a type of device or orthosis for an individual than in the case of a prosthesis for an amputee. An amputation is literally clean cut. Anybody can look at the result and diagnose that the patient is an amputee at a certain level. Any observer knows what is missing — everything beyond that point. Thus prostheses, though individualized, fall into a relatively few major groups. But a patient may require an orthosis from a defect of a long bone, the joints, the muscles, the brain, the spinal cord, or the peripheral nerves; he may or may not have sensory feedback, and he may or may not have spasticity. These variables and their many combinations greatly complicate the problems of design as well as of prescription. Though orthotics problems long have received some attention by intramural and contractual efforts, they are now gaining greater momentum.

The group at the Miami VA Hospital has been involved in a number of basic studies related to spinal cord injury, some of which provide a transition from the preceding papers on electrical stimulation to other experiments as well. (Dr. Ross Davis was unable to attend the confer-

ence, but his colleague, Dr. John Gesink, a biomedical engineer, made the oral presentation.)

Certainly, spinal cord injury, as referred to by Dr. Hofstra, is a major topic for the Veterans Administration. The work for this program includes a variety of devices for control of the environment (lights, TV, alarm, etc.) and for independent mobility. The key point in all this development, since the introduction in England of the POSSUM control, has been the rapid development of new and useful means operating with small excursions and extremely light forces (puffing, sucking, or slight chin motion, head and neck motions, etc.) These systems have been relatively expensive, and it has been only in recent times that anybody was able and willing to spend the money to provide adequate evaluation of their utility in helping the severely handicapped.

Mr. Robert Green, clinical engineer of the VA Hospital Cleveland, describes environmental controls for the severely disabled. Mr. Green represents a new breed of biomedical engineers working directly with patients in the clinical area.

Mr. Lipskin of VA Prosthetics Center has also been involved deeply in the development and the evaluation of these types of environmental control systems, but his topic at this point is on the control of electrically powered wheelchairs by the severely disabled. There are also problems in providing mobility out-of-doors, though not on roadways where both vehicle and driver must be licensed.

Professor Donald M. Cunningham and his colleagues at University of California have worked for a number of years on an ingenious variable-height-powered wheelchair for the quadriplegic or other severely handicapped driver. The original work, under SRS sponsorship, aimed also at curb-climbing and at a mechanism for shifting the chair and occupant into a sedan. Recently, under VA support, the emphasis has been on a versatile chair that can safely be used in vans, and which has other desirable features.

Dr. Jacqueline Perry and Mr. James Allen of Rancho Los Amigos Hospital have recently been working on an ingenious plan to provide both power and controls to fold a hospital bed into a semblance of a wheelchair, thus allowing the severely disabled patient to move independently from his hospital room to recreation and therapy areas. The need for able-bodied staff members to assist the patient in transferring from a conventional hospital bed to a conventionally powered wheelchair would thus be greatly reduced.

Mr. Charles Scott, president of Mobility Engineering, Inc., is already known through his work at the UCLA Prosthetics Education Program to many people in the prosthetics field. Mr. Scott, an engineer, has been working on safety features for holding wheelchairs in vans, has been designing a special van control system to permit versatile and safe

operation by quadriplegics and other severely disabled patients, and has been developing much stronger wheelchairs to resist the deceleration loads which would develop in the event of highway accidents. The VA Prosthetics Center has bought two of Mr. Scott's vans for Castle Point and Long Beach VA Hospitals. Eventually we hope that there will be a group of controls, power lifts, vans, wheelchairs, and experience in evaluating the various combinations. Thus there will be a basis for rational prescription.

Professor Newell of Texas A&M University and his colleagues have been cooperating with VA Prosthetics Center and Texas Transportation Institute on safety during mobility. (Dr. McDermott of Texas A&M University, who has been working specifically on the safety aspects, gave the oral presentation.)

Mr. Martin Prast, a paraplegic veteran, and his father, an engineer, have been fascinated by the possibilities for developing an adult-scale version of the Parapodium designed by Mr. Motloch at Ontario Crippled Children's Centre, Toronto, for children with spina bifida. The Prast Research Associates project aims at a device which the paraplegic can don readily and wear while in a wheelchair. He should be able to rise independently to a standing position and then move on a level surface using an adaptation of the swivel walker principle. Though energy consumption (especially without using crutches) would be much higher than that required for using a wheelchair, the Parapodium concept would allow passage through doors too narrow for a conventional wheelchair. Indeed, freedom of the hands (even if by allowing forearm crutches to hang from forearm clips) would allow use of the hands and arms on door knobs, door jambs, or other features of the environment to assist propulsion as well as to manipulate locks and door latches. The Parapodium would also allow independent standing, movement about a kitchen or an office, and access to cupboards and closets. Alternate periods of standing and sitting should be beneficial in avoiding pressure sores and decalcification of the long bones.

Dr. McDowell, an orthopedic surgeon and consultant to the VA Hospital, Richmond, Virginia, has developed a system for immediate postoperative application of upper-limb orthoses. Originally designed for use on quadriplegics after tendon transfers, the system has also been used after operations for arthritis.

These papers, added to those on electrical stimulation, display a rapid acceleration into relatively new fields, a full range from applied research through development and evaluation to development of safety standards and a pattern of activity to help a variety of severely handicapped patients to be more independent.

TRANSCUTANEOUS NERVE STIMULATION FOR TREATMENT OF PAIN IN SPINAL-CORD-INJURED PATIENTS [a]

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In the following study, 31 spinal-cord patients were tested with transcutaneous nerve stimulation (TNS). The patients ranged in age from 23 to 68 years old and had lesions from C3 to L5. Almost all of the patients required analgesics, such as pentazocine (Talwin, Winthrop), carbamazepine (Tegretol, Geigy), and oxycodon (Percodan, Endo), for relief.

Three different makes of nerve stimulators were used in this study: Medtronics, Stimtech, and Avery. All of these devices were solid state battery-operated pulse generators which delivered variable electrical spikes to a pair of electrodes.

The electrodes used in most cases (Fig. 1) were of our own design (Lentini, Davis, and Goldstein (1)), since those originally supplied with the devices were not as effective or as convenient to use. Conductive rubber electrodes have recently become available, and these were satisfactory in most cases.

We also tested epiconductive silver paint on electrodes and found these to be effective; however, they were time consuming to apply and they had a greater tendency to cause skin irritation.

In our study and treatment of spinal-cord-injured patients with chronic pain, three classifications were made (Types A, B, and C) depending upon which damaged tissues were involved associated with the pain. Type A pain was due to damage to the spinal column and surrounding tissues. This pain was localized around the site of injury. Type B pain was due to damaged nerve roots. This pain radiated along the involved dermatomes. Type C pain was due to damage to the spinal cord itself. This pain is sometimes called central pain and is "referred" from the patients' anesthetic areas.
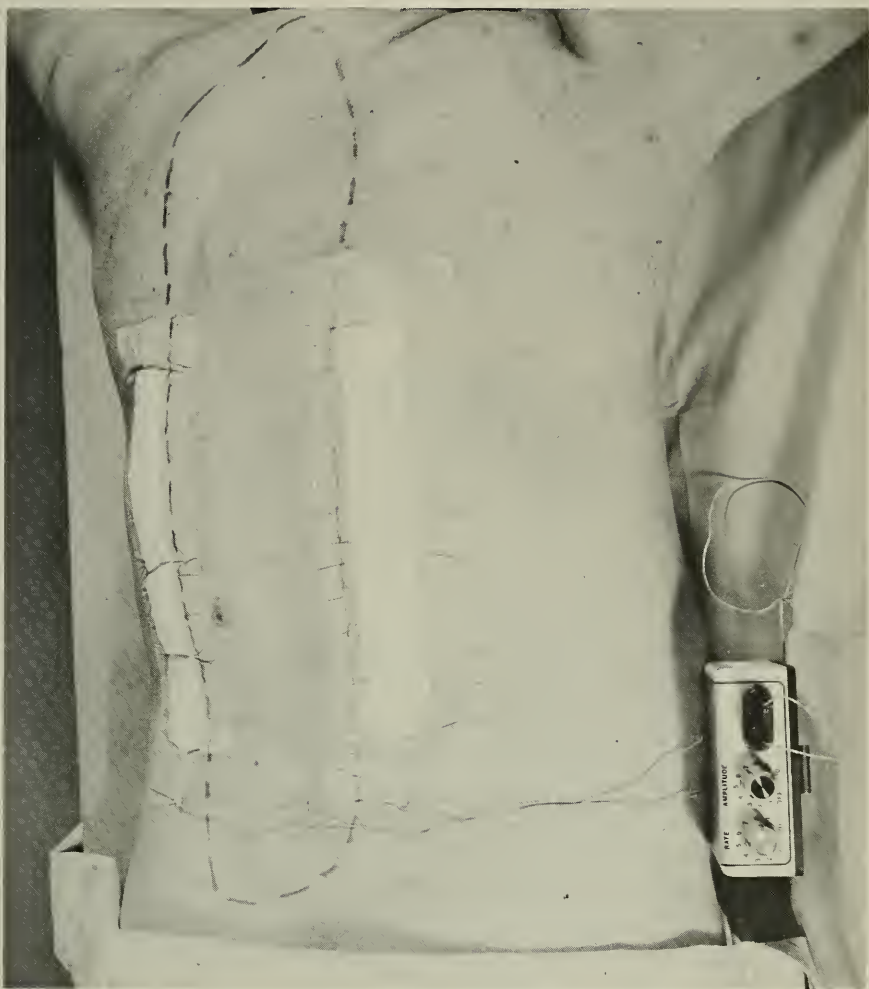
FIGURE 1.—Electrodes designed for TNS are placed adjacent to chronic pain area which is delineated with dotted lines.

Three treatment categories were formed depending upon the amount of relief obtained from the nerve stimulator. There were successes, partial successes, and failures.

In those cases considered "successes," the patient claimed enough relief to warrant wearing the TNS whenever pain was present, and a reduction in the dosage of analgesics was noted. In the "partial success" category, the patients reported some relief, but not enough to want to bother taping on the electrodes and keeping the device with them during painful episodes. The "failures," of course, claimed no relief at all.

Before any of these patients were placed into the above categories, they were allowed to use the device for at least 1 week. Some of the patients were not evaluated until they had the device for over 1 month. The time trial of several days was necessary in order to cancel any possible placebo effect. We found consistent results were not possible unless the patient became thoroughly acquainted with the nerve stimulator feeling and use.

Table 1 shows our results according to the site of the lesion: cervical, thoracic, and caudal. Although few cervical cases were treated, none of these patients responded to TNS. The other two sites responded almost equally to treatment.

TABLE 1.—*Results of TNS Treatments on Spinal-Cord-Injury Patients*
(as to site of lesion)

Injury site	No. of cases	Successes	Partial successes	Failures
Cervical	4			4
Thoracic	11	5		6
Conus, Cauda equina	16	6	2	8
Total	31	11(36%)	2(6%)	18(58%)

Table 2 shows our results according to the type of pain treated. Note that those patients having Type A pain, localized around the site of injury, were more amenable to treatment than the other two groups. Seven out of 11 cases claimed a marked reduction in pain. Patients with Type B pain, radiating along nerve roots, showed little response to the stimulation. Only two of the nine cases were successfully treated.

TABLE 2.—*Results of TNS Treatments on Spinal-Cord-Injury Patients*
(as of pain type)

Spinal Cord Injury Chronic Pain
From Damage To:

A. Spinal Column (localized)
B. Nerve Root(s) (radiating)
C. Spinal Cord (referred)

Type of pain	No. of cases	Successes	Partial successes	Failures
A	11	7	1	3
B	9	2	1	6
C	11	2		9
Totals	31	11(36%)	2(6%)	18(58%)

The most refractory type of pain to that was the central or referred Type C. Only two out of 11 patients responded favorably.

Overall, slightly over one third of the spinal-cord-injured were successfully treated. The importance of this study is that it shows that spinal-cord-injured patients experience at least three different types of pain which respond differently to TNS. More study is needed because TNS as treatment for chronic pain is still in its infancy. Why it works well with some patients and not others is not known. TNS studies on spinal-cord-injured patients with all their subtle variations of paresthesias and dysesthesias may bring valuable insight into the theory and nature of pain.

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EVALUATION OF ELECTRICAL STIMULATION AS A TREATMENT FOR THE REDUCTION OF SPASTICITY [a]

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The purpose of this study is to examine ways in which electrical stimulation, both transcutaneously and via implanted stimulators, may be used to treat spasticity. Spasticity is one of the complications which frequently follows CNS (central nervous system) lesion, and it is commonly identified in the following ways: The involved muscles develop a pathological resistance to passive stretch. This resistance increases with the rate of stretch and also exhibits the "knife-clasp" release phenomenon. The involved muscle groups also exhibit exaggerated flexor and extensor reflexes. Another neuromuscular complication, the muscle spasm (sometimes included as a characteristic of spasticity), frequently accompanies the spasticity of CNS lesion and is often observed in the spinal-cord-injured patient.

Spasticity is generally considered to be detrimental to the patient (1). Gross spasm in the paralyzed limbs of a spinal-cord-injured patient can obviously interfere with activities of daily living. Also, spasm can lead to contractures, dislocation of joints, and can mask volitional control in case of paresis.

Currently, spasticity is managed in a variety of ways (2). These methods include drug therapy, chemical and surgical denervation, physical therapy, and sometimes surgical alteration of tendons. The physical therapy treatment involves passive exercise of the spastic muscles. This treatment, in addition to preventing contracture, has a lasting effect in quieting the spasticity. Apparently, when the paralyzed muscles are exercised, muscle stretch receptors and tendon organs are activated. This sensory information flow into the spinal cord and/or the passive activation of the reflex loop appears to quiet the spasticity. Unfortunately, the therapeutic effect that exercise has on the spasticity lasts only for a period of hours. With electrical stimulation we hope to utilize the same exercise-triggered mechanisms that reduce spasticity in passive exercise. The scheme includes equipping the patient with a portable electrical muscle stimulator. Thus equipped, the patient is free to exercise his paralyzed muscles at his convenience. The potential secondary

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[a] Paper submitted for publication but not presented at the conference.

benefits of this treatment include discontinued use of drugs, with their undesirable side effects, and elimination of the need for regular physical therapy. Also, the electrically exercised muscle acts as a pump returning blood, which otherwise might pool in the legs, to the heart. Because 70 percent of spinal-cord-injured patients suffer from deep vein thrombosis (thrombophlebitis), a condition arising from pooling of venous blood, this secondary effect could be very beneficial.

Our program begins with electrical exercise of recently injured spinal-cord patients with transcutaneous stimulation of motor points and motor nerves. If this phase of the treatment shows promise, the patient is considered for implantation of a permanent radio-frequency coupled transmitter-receiver-type electrical stimulator. The electrodes of the implanted receiver are placed around the motor nerves, and the transmitter is worn on the patient's belt.

Thus far, effectiveness of the treatment has been evaluated subjectively with the aid of a standard neurological examination. Here, judgments are made regarding changes in the indicators of spasticity, such as resistance to passive stretch, strength of the stretch and flexor reflexes, and duration of clonus. We are also in the process of developing two additional measures to evaluate the effectiveness of the treatment. Both of these measures are attempts to define changes in spasticity in as quantitative a manner as possible. The first of these two measures is the reflexogram. Our use of this measure is based on the knowledge that the stretch reflex is a primary indicator of level of spasticity. Calibrated taps are delivered to the Achilles tendon with a motor driven hammer. The resulting isometric torque produced by the stretch reflex is measured with a torque transducer attached to the foot. Both the tendon tap and the isometric torque are recorded on FM tape for later processing by computer. The second measure we are employing to quantify level of spasticity is the standard H-reflex (3). This reflex, except for bypassing the muscle spindle, follows the same pathway as the Achilles tendon stretch reflex. Use of this reflex as a diagnostic tool is standard practice (4). Also, its use as a measure of motor neuron excitability, a prime indicator of level of spasticity, is common and is well documented (5).

Our progress to date on this project includes a paraplegic patient who has been implanted with bilateral peroneal nerve stimulators (Oct. 1972). The equipment used in this case was a portion of Medtronic Neuromuscular Assist Device (Fig. 1) which has been developed to correct the footdrop condition that frequently accompanies hemiplegia. This device is supplied with a cycling module which may be used to exercise paralyzed muscle. In this case the anterior tibial groups of both legs were exercised. Because our objective measure of spasticity (reflexogram and H-reflex) had not yet been developed when this

patient received his implant, only the subjective evaluation of the changes in his spasticity was made. This evaluation indicated a significant reduction in the clinical indicators of spasticity. In addition to these primary effects, an additional beneficial side effect was noted. The electrical exercise initially arrested atrophy of the stimulated muscle, and as time passed, resulted in an increase of muscle mass not only of the stimulated muscle but also of the adjacent musculature above the knee (Fig. 2). Further, the patient was able to discontinue the use of muscle relaxant drugs as well as regular physical therapy sessions.
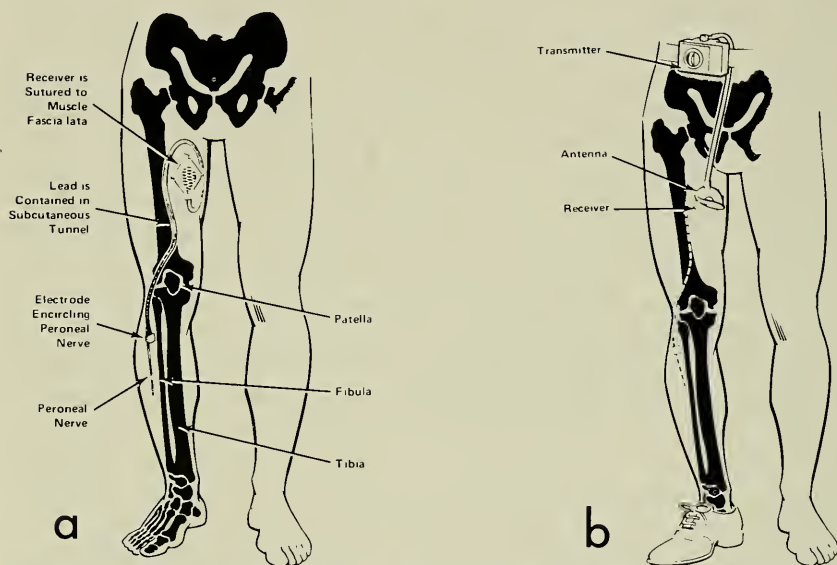
FIGURE 1.—Scheme illustrating method used to electrically exercise the paralyzed musculature. a. Receivers, lead, and peroneal electrodes are implanted in the patient. b. Battery-powered transmitter is worn on a belt and an antenna is taped over an implanted receiver. Copyright 1972 by Medtronic, Inc. Reprinted with permission.

Our immediate plans for the future in this part of our research include providing a second paraplegic patient with an implanted bilateral peroneal stimulator system similar to the one shown in Figure 1. Evaluation of the effectiveness of the treatment in this patient will include the use of both our subjective and quantitative measures.

The above study constitutes only part of our effort in evaluating the effectiveness of electrical stimulation for the treatment of spasticity. The
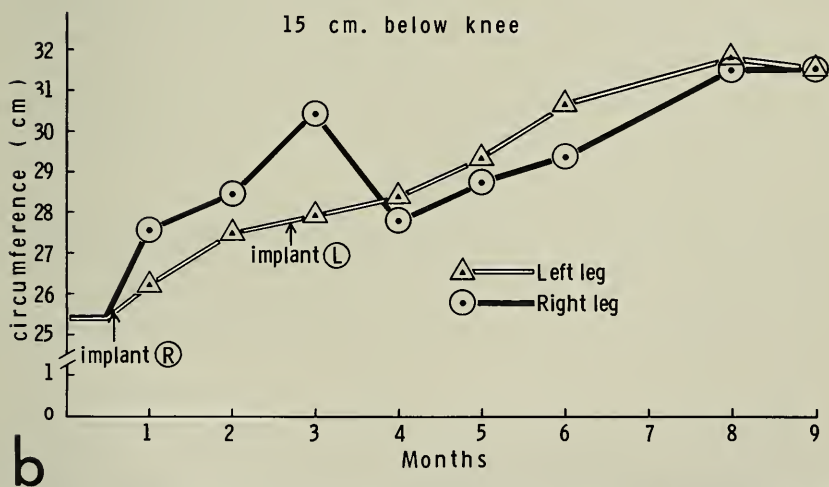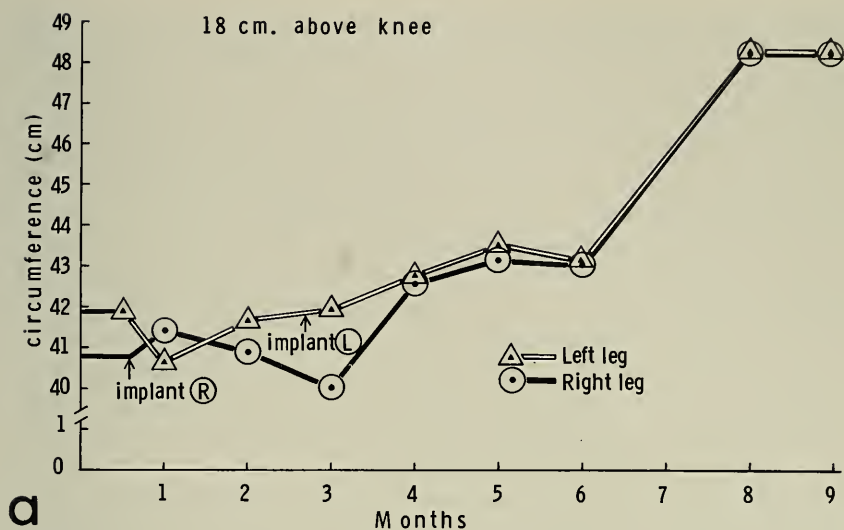
FIGURE 2.—Data illustrating hypertrophy of the leg following regular electrical stimulation of the peroneal nerves with implanted electrical stimulators. Hypertrophy is indicated by an increase in leg circumference. a. Circumference of the leg at a level 18 cm. above the knee. b. Circumference of the leg at a level 15 cm. below the knee.

second part of our effort is aimed at treating the spasticity that frequently follows severe brain damage such as cerebral palsy, stroke,

and head injury. While this type of spasticity (cerebral spasticity[b]) has many characteristics that are similar to spinal spasticity, there are several differences. Spasticity of cerebral origin is frequently less violent and more regular than that arising from spinal lesions (2). Also, cerebral spasticity frequently masks voluntary muscular control, while in spinal spasticity, because the neural pathways for volitional control are frequently transected, there is no control left to mask.

Thus, successful treatment of cerebral spasticity potentially can be doubly beneficial in that it both reduces the spasticity and unmasks voluntary control. Many of the current treatments for cerebral spasticity are the same as those already discussed. Medication such as Valium (Roche), Dantralene (Eaton Laboratories), and other muscle relaxants have been partially successful with mild and moderate spasticity. Physical therapy and stereotaxically placed deep thalamic and cerebellar lesions have also been used to manage the spasticity. Very recently a treatment using electrical stimulation has been described (6). This treatment involves electrical stimulation of the cerebellum through electrodes placed directly on its cortex. The rationale for this treatment is based on a broad spectrum of neurophysiological studies which indicate that the cerebellar cortex acts as a significant inhibitor of the rest of the brain (7). This powerful inhibitory influence of the cerebellum was demonstrated before the turn of the century by Sherrington (8) who showed that decerebrate rigidity in cats could be inhibited by stimulation of the anterior cerebellar cortex. More recently, Moruzzi (9) observed that the stimulation of the anterior cerebellar cortex could increase or decrease decerebrate rigidity depending upon the frequency of stimulation. He found that a frequency of 100 to 300 Hz decreased rigidity while a frequency of 10 Hz resulted in an increase.

These and other observations led to the conclusion that the cerebellar cortex acts primarily in an inhibitory capacity, and that this inhibitory function can be increased and modulated with chronic electrical stimulation. The pioneering work in implanting cerebellar electrodes for chronic stimulation of the cortex was done by Cooper (6). He has

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[b]It should be noted that all spasticity originates in the spinal cord and is the result of a hyperexcitable reflex loop. The hyperexcitability, however, can result from lesions at any point in the CNS. The terms "cerebral spasticity" and "spinal spasticity" thus refer to the location of the lesions which resulted in the hyperexcitability at the reflex loop.

reported at least 32 cases where the treatment was beneficial in reducing chronic cerebral spasticity.

The aim of our effort in this project is to continue and extend the work of Cooper. Thus far we have moved toward this objective by developing a new technique which significantly reduces the complexity of implanting the cerebellar stimulators (10). Using the technique, we have implanted two patients suffering from cerebellar spasticity. In both cases, two arrays of silicon rubber-backed platinum button electrodes were used (Fig. 3). In the first case, the electrodes were placed on the anterior and posterior lobes of the right cerebellar cortex (Fig. 4). In the second case, the electrodes were placed on the anterior cerebellar lobes bilaterally. Electrical stimuli were delivered to the electrodes by means of a transcutaneous RF-coupled transmitter-receiver system supplied by Avery Laboratories (Fig. 3). Eight minute bursts of stimulus at a rate of 200 Hz were delivered alternately to the two electrode arrays. Stimulation was continuous. At this time we are still evaluating the effectiveness of the treatment in reducing the patient's spasticity. Preliminary subjective observations in the first patient indicate an improvement in speech and in gait and, in both patients, a somewhat reduced level of spasticity. H-reflex measurements on the first patient were made both pre- and post-implantation. These measurements indicate that the stimulation produced a decrease in spasticity, in that they showed a significant reduction in H-reflex detectable motorneuron excitability.

While our study of these two patients is not yet complete, our observations and measurements have led us to a number of conclusions regarding the cerebellar stimulation treatment. First, the treatment appears to be most effective when the electrodes are placed on the anterior cerebellar cortex. Second, placement of the electrodes on the posterior cortex has no detectable effect on reducing spasticity. Our third finding is that the beneficial effects of the treatment can be achieved even when the stimulation frequency is reduced from 200 Hz to 100 Hz. This reduction is beneficial in that it significantly reduces the rate of discharge of the batteries of the patient-worn transmitter.

Because this procedure appears to provide some relief from a pathological condition for which there are not other proven treatments, we plan to extend the study. Additional patients with cerebral palsy and dystonia are being considered for implantation and study. Also, followup studies are continuing on those patients who have already had an implant.
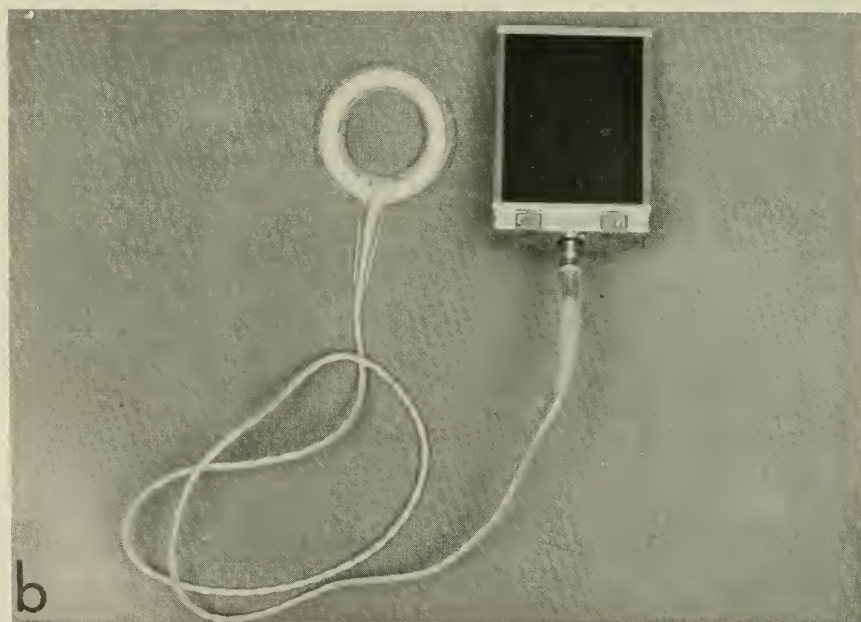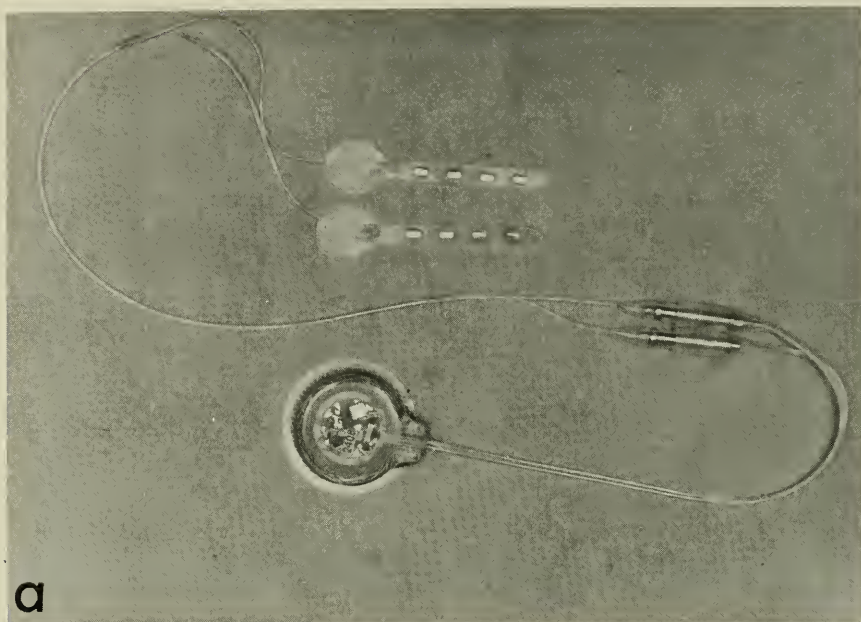
FIGURE 3.—Transmitter and implantable receiver—electrode system used in chronic electrical stimulation of the cortex. a. Implantable receiver, leads, and platinum button electrode arrays. Electrodes are placed on the cerebellar cortex. A receiver stimulator is implanted in the clavicular region. b. Battery-powered transmitter and antenna of stimulator system. The antenna is taped over the receiver.

FIGURE 4.—X-ray illustrating placement of chronic cerebellar stimulating electrodes arrays on the anterior and posterior cerebellar cortex.

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THE CURRENT STATUS OF AND FUTURE CONSIDERATIONS FOR ENVIRONMENTAL CONTROL SYSTEMS

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INTRODUCTION

This paper deals with the new environmental control systems for high level (C-3, C-4, C-5) quadriplegics. These systems are dynamic because the field is new and one can only begin to envision their potential. Through simple and easy-to-use actuators, the spinal-cord-injured patient can dramatically acquire an effective level of independence.

Included in this paper is a generalized description of an environmental control system; specific systems are later studied within the framework of a generalized system. The last section includes suggestions for further development and improvement of capable environmental control systems.

ELEMENTS OF AN ENVIRONMENTAL CONTROL SYSTEM

An environmental control system is an electronic system which accepts a voluntary action within the patient's realm of activities as input and converts it into the operation of some device. Figure 1 breaks down an environmental control system into its component parts.

The transduction element is the crucial element of the system that converts the patient's response into an alteration of the condition of an electric circuit, resulting in the generation of an electric signal. Examples of transduction elements are: minimal force-actuating touch switches (microswitches) for hand or tongue control; air switches for breath control; sound sensors sensitive to a narrow range of frequencies for voice control, such as whistling at a certain pitch; light sensors for eye control (a light source and a sensor can be positioned on a pair of glasses so that the source points its beam and the sensor picks up reflected light from the corner of the eye. When the pupil moves to the specific corner of the eye, the reflected light is greatly reduced, thus generating an alteration in the state of an electric circuit); and a myoelectric sensor utilizing the electrical potential generated by the stimulation of a muscle along an intact nerve.

ELEMENTS OF AN ENVIRONMENTAL CONTROL SYSTEM
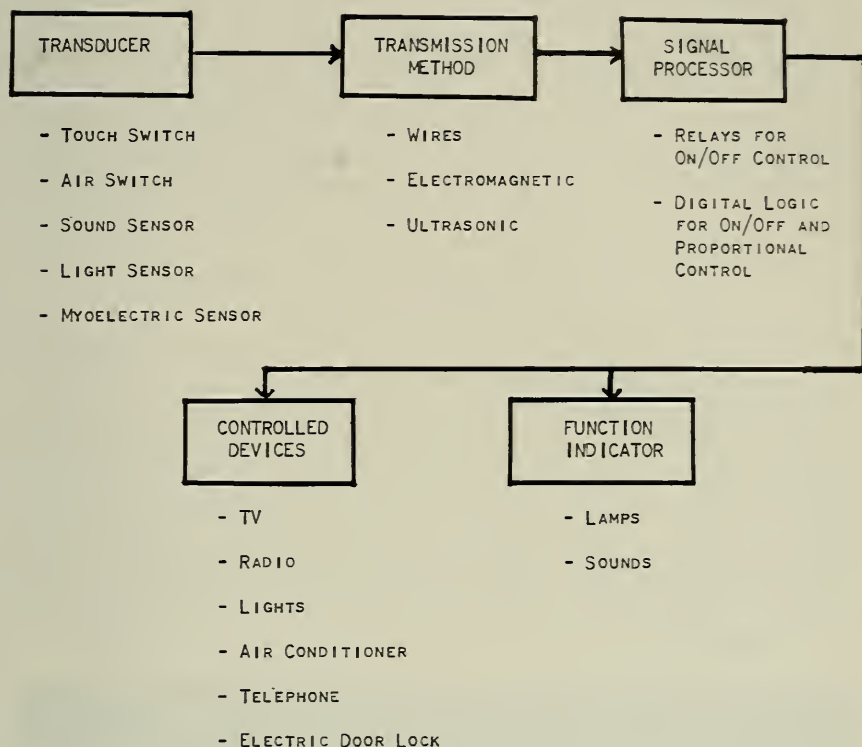
FIGURE 1

The next element of the total system is the transmission mechanism which sends the signal generated by the transducer to the signal controller. Most systems employ direct electrical connections as the simplest and cheapest technique. Other modes of transmission can be wireless, either through electromagnetic or ultrasonic energy. These latter methods increase an evironmental control system's potential.

The brain of an environmental control system, the signal processor, processes the signal from the transducer and places the system in a new desired state by operating a device or appliance. Depending on the capability of the system, the processor may range in complexity from a few relays to a sophisticated digital logic system. A simple processor can effect on/off control of a device, while a high-level unit can initiate proportional control as well. Examples of proportional control are the channel and volume controls on a TV or radio, and the height control on a bed.

The output elements are the devices controlled by the signal processor. Examples of these devices include: alarms or nurse calls, televisions, radios, electric door locks, special telephones, lights, air conditioning units, or any other electrical device.

Finally, an environmental control system needs a feedback element. The system must inform the user what state the system is in. The user must be aware of the result of his next encounter with the system. The most common indicator element is a set of lamps. Another form of feedback is an audio mechanism that generates a sound at a unique frequency for each function that the system performs.

EXISTING ENVIRONMENTAL CONTROL SYSTEMS

Now that a general description of environmental control systems has been given, a discussion follows of some of the current systems in use.

Figure 2 shows the Prentke-Romich Paratrol. The signal processor energizes or deenergizes four standard receptacles. The transducer can be either two types of touch switches or an air switch. By activating the transducer and maintaining it in the activated state, the processor sequentially cycles control capability to each of the four outlets. A bulb illuminates above each receptacle when the processor sequences to that receptacle. Releasing the transducer causes the processor to stop cycling and to change the state of the receptacle whose monitor bulb was

FIGURE 2

illuminated last. The state of a receptacle is maintained during the cycling stage and is not altered until the user releases the transducer at that receptacle. The cycling rate can be easily adjusted with a front panel knob to meet the needs of the user.

Some positive features of this system include the multiplicity of transducers available that enable the system to be used by various types of patients. The cycling speed can be adapted to the patient; in this way, the system need never be too fast or too slow for the patient. The system is small, light, simple to setup, easy to use, and easy to adjust; however, it has limited capability. Its cost is $180.

Figure 3 shows the Prentke-Romich automatic dialing telephone. This is not an environmental control system in the sense discussed, but the telephone has some features worth mentioning. The unit can either stand alone or be easily controlled by an environmental control system. Once the device is energized by hitting the left side of the rocker switch, the user can dial the phone by holding down the right side of the switch. The digits cycle from 1 to 0 at an adjustable rate. The user releases the switch when the desired digit is displayed on the screen. One version of this telephone has the advantage that in the event of a power failure, rechargeable batteries power the unit. Thus, the user can feel safe that his communication medium will remain operational for emergency use.
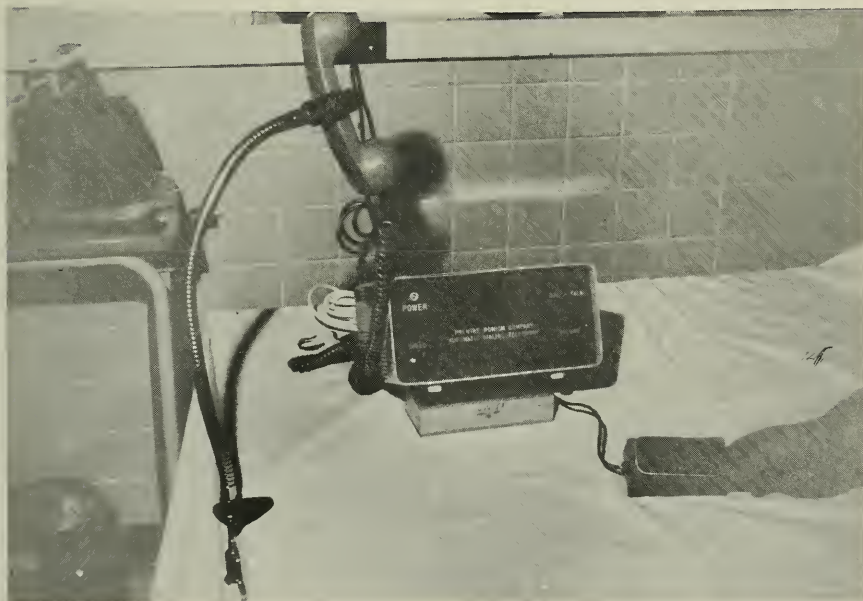
FIGURE 3

The next device, a typewriter controlled by a light source (Fig. 4), is also an assistive device rather than an environmental control system. The firm that makes this device also makes an environmental control system. Both units use the same name PILOT. The transducer is an example of a light-actuated device. The user wears the light source and shines it on the desired letter, behind which a photocell generates the necessary signal. The processor then types the letter. Once the unit is on, the user can control the speed at which letters are typed. There are three delay settings—maximum delay, minimum delay, and no delay—which determine the reaction speed of the processor to the new input. Thus, the user can learn the system at a slow typing speed and build up his speed with practice. The main disadvantage is that the transducer has poor cosmesis.

FIGURE 4

The SONOTROL system (Fig. 5) uses a controlled-sensitivity air switch as the transduction element. The processor can control 10 channels. The system starts selecting channels at an adjustable cycling rate when the processor perceives its first puff. A second puff stops the sequencing at a specific channel. If the sequencing stops at channels 1-5, power is supplied to an appliance. If channels 6-10 are chosen, the state of the appliance changes from either off-to-on or on-to-off. Each of channels 1-5 can be on only if the processor is controlling that channel. If channel 2 is activated and a puff causes the processor to start cycling, channel 2 will deactivate.

This system has been evaluated by patients at the Castle Point VA Hospital, and the response was not positive. The two types of logic can be confusing, thus limiting the value of channels 1-5. However, there is one feature of this system which has great potential. Figure 5 does not indicate this, but the processor activates devices by transmitting an ultrasonic signal to a receiver which is at the appliance site and is not connected to the processor. This supports the idea that the processor can be modularized to increase the capability of the system when desired. In addition, since the signal processor need not be a single package, the amount of hardware directly surrounding the user can be reduced. This system costs approximately $1,000.
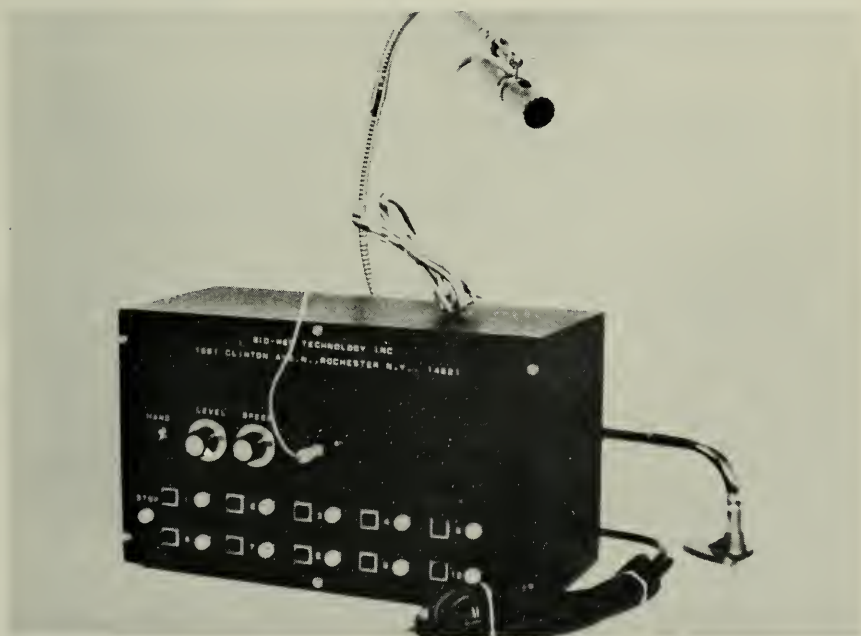
FIGURE 5

The POSSUM system (Fig. 6) is the oldest environmental control system. The transducer can be either an air switch or a microswitch. Continuous activation of the transducer causes the processor to cycle at a fixed rate through 12 channels. Deactivation of the transducer causes the cycling to stop and the state of the selected channel to change. An appliance is thus either energized or deenergized.

FIGURE 6

The final three systems employ processors which have proportional control features; the state of an energized device can be altered other than by just deenergizing the unit.

The first system is the Hayes Sight Switch Environmental Control System (Fig. 7). This is a 10-channel system. The transducer is not shown, but it is the special pair of glasses described earlier. This system requires two light source-sensor elements on the glasses. Movement to the upper left corner by the left eye causes the system to cycle to a sequential channel and to remain on that channel. Another movement cycles the system to the next channel. The right eye initiates the operation controlled by the selected channel. On/off control can be effected, or the system can control the volume and channel on a remote control TV, the height of an electric bed, and any other device that can be adapted to the system.

This system is definitely more powerful than the previous systems, but the method of transduction seems to be somewhat fatiguing. To raise an electric bed or change the TV volume, the right eye must remain in the corner until the desired state is reached. This can be uncomfortable for

the user. Furthermore, the user must be careful where he looks so as not to unintentionally activate the system.

Hayes has an idea that should be evaluated, which involves a portable five-channel system built into an attaché case. A mobile system obviously need not restrict a patient to control of appliances in one room only; a user could take his control system to his job. Currently, Hayes is having some engineering problems with these systems.
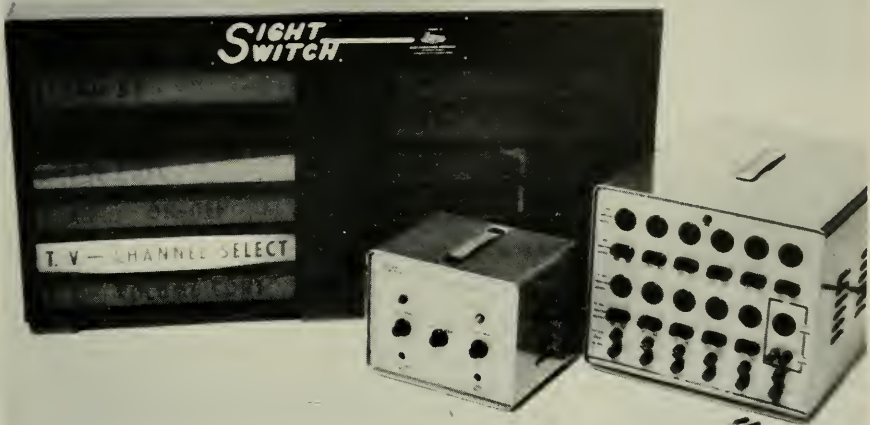
FIGURE 7

The VAPC Hospital System (Fig. 8 and 9) is a 12-channel system which uses a tube connected to two air switches as the transduction element. Sipping results in sequencing through the channels, while blowing alters the state of an appliance. A loaded VAPC system can control the volume and channels on a special radio, the channels on a remote-control TV, the height and the position of the head on a Simmons electric bed, a nurse call request, a special audio-visual emergency alarm. It also can supply power to four other devices. This system also includes up-down indicators for the radio channel and volume.

Unlike some of the other systems, the user does not have to maintain activation of the transducer to operate a proportional function. The user puffs to start a change and puffs when the desired final state has been reached. Each proportional function has three cyclic operational modes: down, off, and up. If, for example, the user wants to increase the radio volume, he puffs on his tube. The radio volume indicator may show a decrease in volume. A second puff would cease operation, and a third puff would result in increasing the volume.

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The VAPC system is a high-performance system. A communication device, a telephone, could be added to the system easily. One good feature is the box of push button switches which enables people other than the user to operate the system. The system is well-engineered, but the main components are electronic relays which cause unpleasant noise when they switch states. Another problem is that the user must remember to shut off the motors that operate the bed and the radio. If, for example, the bed is lowered to its lowest position, the user may forget the motor is still running and blow a bed circuit breaker. Limit switches on these functions would be a worthwhile addition. The cost in limited production is about $800.

The Bioengineering Research Service has gone a step further and designed a 20-channel system for home use (Fig. 10). With 20 channels, this system can perform more functions than any existing system. The major difference is that the processor has only two 115/volt outlets, 11 outlets (the majority) are low voltage outlets, and the balance are switching jacks for low voltages. However, these low voltage outlets can be used to energize and deenergize appliances. The key to the system is a module which plugs into the outlet formerly used by an appliance. The appliance plugs into the module which is controlled by a low voltage outlet. The object is that one does not need to run powerline cords all over a room; instead, low voltage wires can be used. Hence, the system design provides a great deal of safety from potential electrical hazards such as cracked insulation on a high voltage cable. The advantage of this design is its modularity. To meet the specific needs of each user, special external modules can be designed. However, the main body of the processor requires no alteration. Thus, the main body of the processor and a few types of common modules can be mass-produced at the lowest possible cost. Customers would then have the option of buying either a relatively
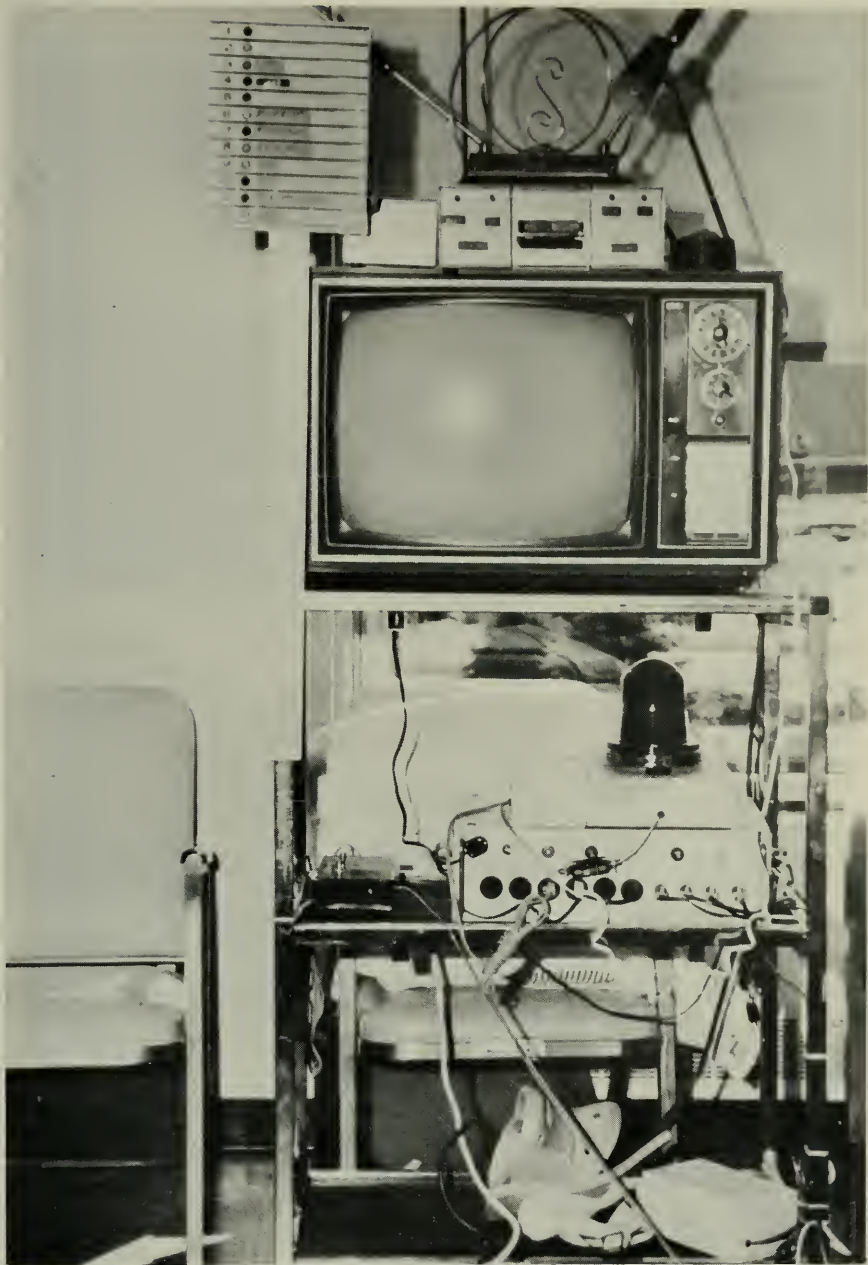
FIGURE 9

inexpensive standard system (the cost in limited production is about $1100) or a more expensive customized system.

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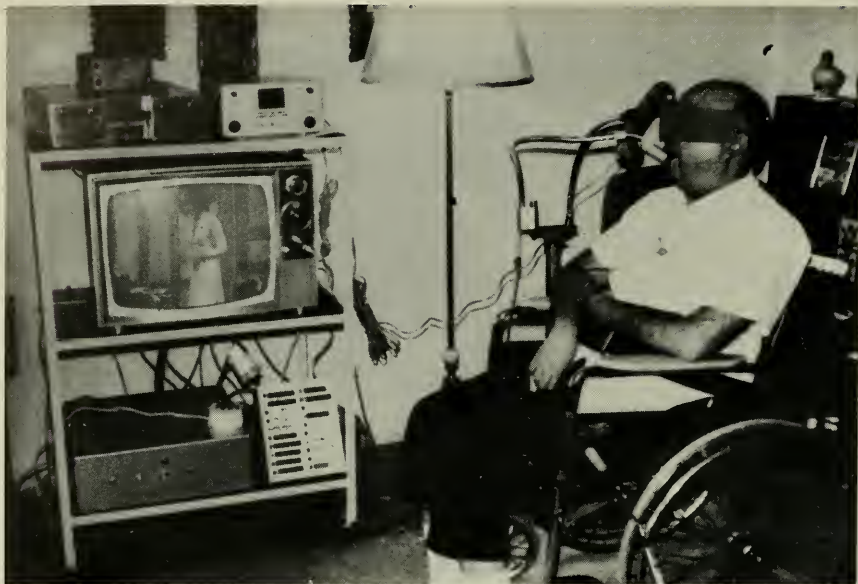
FIGURE 10

The third version of the VAPC environmental control system is the wireless system (Fig. 11). The air switch generates a signal which is transmitted to the main body of the processor via a transmitter. In this case, the transmitter is a garage door controller. The transducer and the transmitter are not tied to either the processor or any power source. The utility of this idea is that the patient can be anywhere in the room and be able to control his system, as long as he has his transmitter. As a result the user is given a greater degree of freedom. So far only a laboratory model has been built.

The final system is the Northwestern University Comfort and Communication System (Fig. 12). It is a well-designed, solid state control system capable of performing eight functions. The system employs air switches for pneumatic control. The user sips and puffs on a straw which in addition to being simpler and cheaper to use than plastic tubing, can be utilized because of the unique arrangement of the system. The monitor and the decoding portion of the processor are enclosed in the module above the patient. The module is attached to an adjustable arm which is mounted with a C-clamp.

FIGURE 11
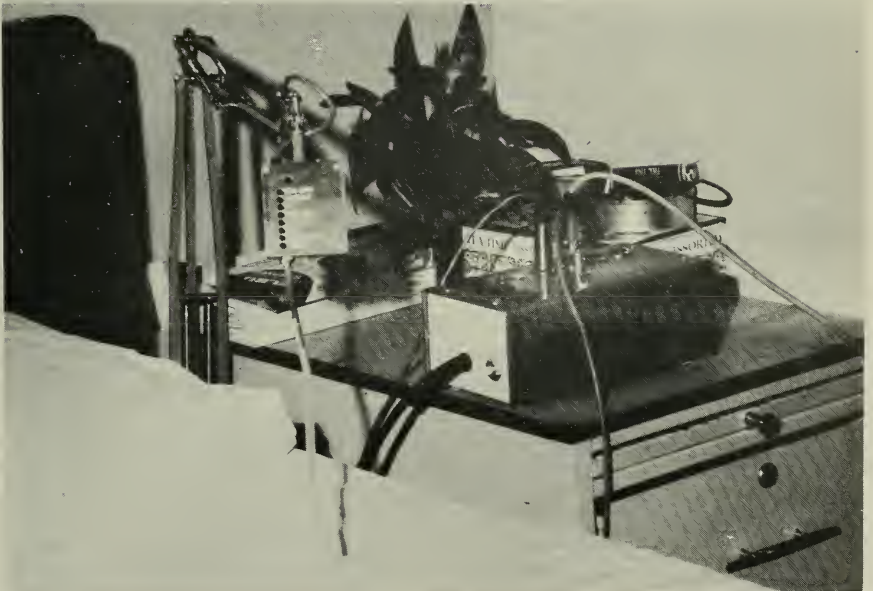
The system is operated with a control coding opposite to the VAPC system: puffing changes control functions and sipping operates devices. Three 115-volt outlets energize and deenergize appliances. The system performs five more functions: operation of a speaker phone, changing TV channels, operation of a nurse call system, height control of an electric bed, and operation of an electric page turner.

The major advantage of this system is its small size and low weight. It operates more quietly than the VAPC system's noisy relays. The miniature monitor near the user has merit. The monitor has an additional light which indicates whether the current function is "on" or "off." There are parallel pushbutton switches for use by an aide. Some of the disadvantages of this system are: the user can only dial the operator, suction must be maintained to raise or lower the bed, and the page turner function has not operated properly due to the poor quality of existing page turners. The estimated cost for this system is $700.

CONCLUSION

The systems that have been discussed are indicative of the current state of the art. Now it is necessary to decide whether the premises on which these systems were built generate systems that most optimally meet the needs of the quadriplegic. The answer is probably not. However, no one can really say for sure, because the performance of these systems is difficult to evaluate. The development from no control to the ability to operate a few devices is more than enough reason for a patient to proclaim the system a success. The problem is that the patient, the major source of information, is uneducated with respect to environmental control systems. Before he can provide useful information, he must experience a number of systems which include the unique features of some of the systems that have been discussed. Hence, a study that utilizes more experienced patients will have to be made to determine the optimal design parameters for an environmental control system.

The study should consist of exposing each person in a group of psychologically sound, intelligent volunteers to at least three or four different systems for a reasonable period of time, about 3 to 5 weeks. The user must evaluate each system immediately after completing his testing period with it. This evaluation should include a questionnaire specially designed to extract from the user the advantages and disadvantages of each system, and any additional functions that he feels environmental control systems might perform. After each subject has sampled all systems, he should compare the systems as a group. Finally, the subjects should be brought together to share their thoughts and to generate new suggestions and criticisms. The best results could be

obtained if the study were conducted with subjects using the systems in their homes, but the logistics make the idea unfeasible.

To reiterate, the purpose of such a study would be not to find the most useful existing system but to determine what the most useful future system should entail. At Cleveland, we plan to attempt a small pilot study patterned after these thoughts. The VA spinal-cord-injury centers provide enough subjects and support personnel to generate statistically significant data; the VA Prosthetics Center might coordinate such a project. Educating a group of people by the process of experience and then acquiring their thoughts is the most direct method for determining the design parameters for the next generation of environmental control systems.

Although we do not yet have the feedback we would like from the users of these systems, the following are some suggestions that I would like to pose for consideration:

1. *Multiplicity of Transducer Inputs*

All environmental control systems should be capable of accepting a multiplicity of transducer types to meet the needs of as large a population as possible. Parallel pushbutton control to enable an aide or a member of the user's family to operate the system should be a standard convenience feature for all systems.

2. *Ease of Setup and Adjustment*

The system should be designed so that a nontechnical person can set it up and adjust it without the system incurring damage due to incorrect assembly. The more complicated the system is for the family to construct and operate, the less willing they will be to promote the use of the system. (Currently, this does not present a problem, because the setup process is a one-time experience and only a few of the systems have any adjustments at all.)

3. *An Operational Mode to Combat an Internal or External failure*

These systems should be designed with the capability of being operational in the event of an internal or external failure. All systems should have some type of battery-operated failure mode which controls a communication device, a telephone, or an alarm. For example, the Prentke-Romich telephone will operate with battery power in the event of a power failure. Thus, the user need never lose his power of communication and so he gains a greater degree of confidence in his system.

4. *Modular and Expandable*

The systems should be modular and expandable. The building-block approach lends itself to cheaper, more flexible systems. The needs of each user vary, and larger systems with greater capability are not necessarily the answer. We cannot yet say exactly how many channels an average system should contain.

5. *Minimal Size and Weight*

Minimal size and weight is desirable. The Northwestern system appears to be a good design goal.

6. *Electrical Safety*

The need for a safe design is obvious. Both Sonotrol and the VAPC system reduce the number of high voltage power cords that must run to the processor. The units should meet all national safety standards for electronic devices.

7. *Reasonable Cost*

Cost is always a determining factor. A reasonable upper boundary for the cost of an environmental control system is $1000. Prentke-Romich's $180 system offers limited capability, but the price makes it accessible to a majority of the population.

8. *Mobility*

The last design criterion, mobility, seems to be the most important parameter. Currently, most systems limit the user to one location. For example, a standard VA Prosthetics Center system configuration has gooseneck tubing which supports the tube mounted on the user's bed. Whenever the user is out of bed, he is just as dependent upon an aide or family member as before; in order to maintain his level of independence, the user must stay in bed. The system thus induces tendencies which defeat its purpose. However, with the addition of a small transducer-transmitter module to the system, the user can control his system no matter where he is in the room. Futhermore, if the receiver-processors were small, modular 10-channel function controllers, the user could take his portable transducer to any room with a processor and control devices. If the whole system were portable, the user could take his transducer and a processor to his job where the devices he uses are specially adapted to his system. Another benefit of total mobility is a processor module which enables the environmental control system to operate an electric wheelchair. Mobility is the key to augmenting the therapeutic value of environmental control systems.

The ideal system based on these criteria would have a transducer-transmitter module capable of utilizing a number of transducer types. The module would be small and battery-operated. The processor would be comprised of small, portable building-block modules which control 10 functions. The blocks could stand alone or be interconnected to provide increased capability. The ouputs of the processor would be low voltage signals operating external modules which control the appliance or device. This system would be more ideal if the processor blocks transmitted the signals to the device-control modules.

If the VA Prosthetics Center were to use the transmitter-receiver approach on their home system, and if they converted the hybrid to a solid-state, modular, portable system, they would have a near-ideal sys-

tem. This system is not beyond their capabilities, and its potential applications would be limitless.

In conclusion, environmental control systems can have a greater potential for rehabilitation than demonstrated by current systems. We must set and meet higher goals of rehabilitation for these systems.

VA PROSTHETICS CENTER PROGRAM FOR ELECTRIC WHEELCHAIRS AND OTHER NONLICENSED MOBILITY AIDS

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This program, conceived approximately 3 years ago, was initially directed toward evaluation. Its primary purpose was to clinically evaluate all known commercially available devices, as well as relatively new designs emerging from a number of research and development laboratories. Ultimately, evaluation was to serve as a basis for possible new designs and developments.

At the inception of this program, only conventional electric wheelchairs were used for evaluation. The standard wheelchair was, and presently is, the Everest & Jennings "34" Power Drive, commonly used for indoor and institutional use, but occasionally for outdoor travel. It became apparent, after reviewing the commercial models available from Everest & Jennings, Invacare, and Motorette, that certain performance requirements were evidently lacking from patients' viewpoints. Severe maintenance problems also existed for the professional staff. For instance, many of the younger veterans are highly motivated to return to the university to continue their education. Others are in search of vocational opportunities. Common to both group's needs is the need for a higher performance wheelchair to provide increased speed, improved ramp climbing capability, superior battery performance and greater life expectancy. Relative simplicity in maintenance and repair is absolutely necessary, since qualified technical support is uncommon.

The VA Prosthetics Center considered modular package design in order to reduce the need for electronics and other technical support. Ultimately, the modular package will permit rapid plug and socket electrical connections and the use of basic hand tools, such as screw driver and wrench, which will permit physical removal and replacement of malfunctioned components.

After approximately 20 months of development effort, one motor package emerged that offered apparent superiority over all other types considered. This new development was based upon the use of printed

motors (Fig. 1) and exhibited exceptional electrical efficiency, excellent performance characteristics, and a high level of reliability.
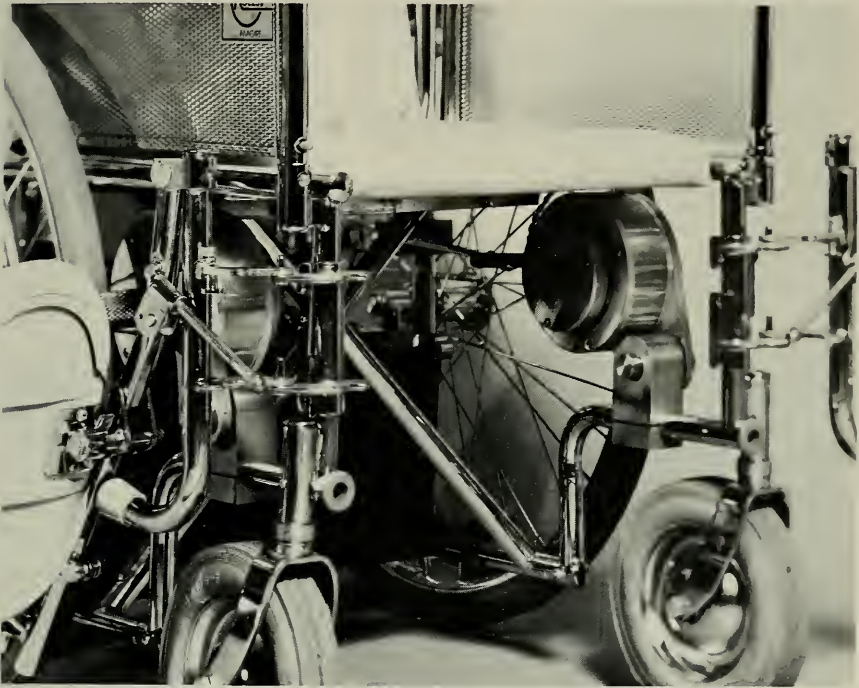
FIGURE 1.—Printed motors mounted on wheelchair.

A proportional joy-stick-operated electronic controller was developed for these motors, which is presently in final development stages. Approximately 35 printed-motor powered wheelchairs (Fig. 2) have been distributed to 12 VA Spinal Cord Injury Services and, from patients' viewpoints, are being extremely well received. The chairs' power packages have performed reasonably well during a trial period and have proved the efficacy of modular design. The modular package facilitates rapid maintenance and repair which has permitted the evaluation to proceed quite simply on a "mail order business" arrangement with participating VA Hospitals.
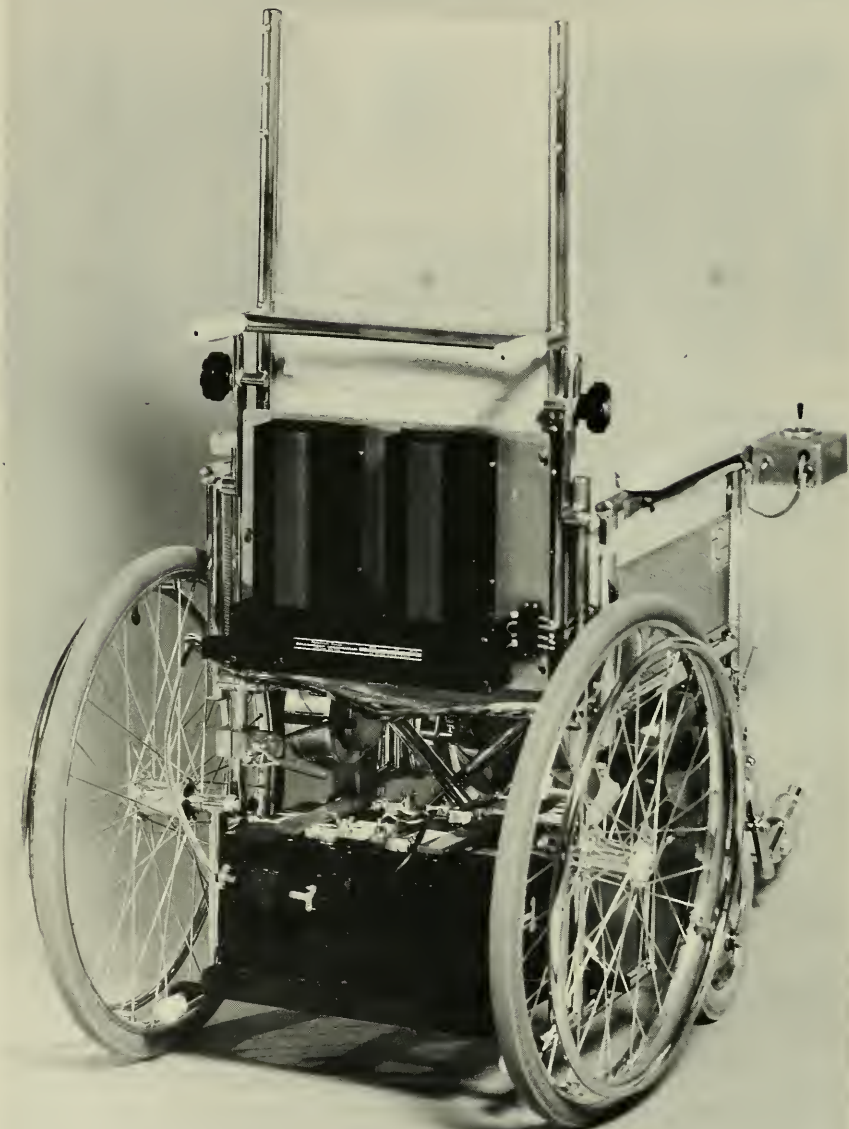
FIGURE 2.—Printed-motor-powered wheelchair.

Our Center has received several requests for improved electric litters. We have introduced electrically powered litters that incorporate the

printed motor design (Fig. 3) with proportional control into a few Spinal Cord Injury Services. These motors, in combination with strategic location on the chair, clearly show that these improved litters provide superior performance. Normally, the steering, achieved by placing a conventional joy-stick control over the main drive wheels, results in a "fish-tailing" phenomenon. Poor performance also results, since conventional wheelchair motor packages are used. The use of printed motors and strategic placement of the direction controlling joy stick over the small swivel casters result in considerably improved performance and steering capability.

FIGURE 3.— Printed-motor-powered litter.

Our Center's evaluation and development effort has also led to the opposite end of the performance spectrum in order to meet the continual request for a lightweight, portable, and truly foldable electric wheelchair. We have made use of small torque motors produced by a sister organization of the manufacturer of the printed motors. The VA Prosthetics Center was successful in fabricating a lightweight power package with a miniature joy stick (Fig. 4 and 5). However, performance was markedly reduced and no patient was interested in using the experimental chair over an extended period. Therefore, further evidence was received that additional effort had to be devoted to the development of a higher performing vehicle which retained substantial wheelchair characteristics.
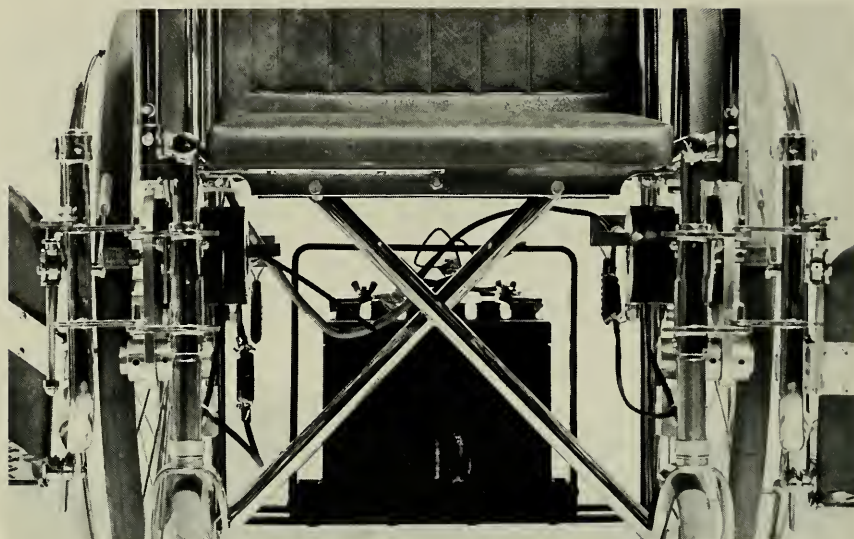
FIGURE 4.—View of lightweight power package for wheelchairs.

FIGURE 5.—Lightweight power package wheelchair showing miniature joystick.

Conventional powered wheelchairs are generally used by paraplegics and low-level quadriplegics. However, high level quadriplegics also enjoy access to these powered wheelchairs, as well as the higher performing printed motor units, via a family of special control devices developed by the VA Prosthetics Center. For those patients who are unable to effectively use their hands and fingers for hand-operated joy sticks, a chin control design is now available. The VAPC Chin Control unit (Fig. 6) is comprised of a rigid bracket providing anterior-posterior, medial-lateral, and vertical adjustment through an assembly of joints and clamps. A swivel joint (Fig. 7) facilitates patient introduction to and removal from the wheelchair.

FIGURE 6.—VAPC Chin Control for electric wheelchairs.
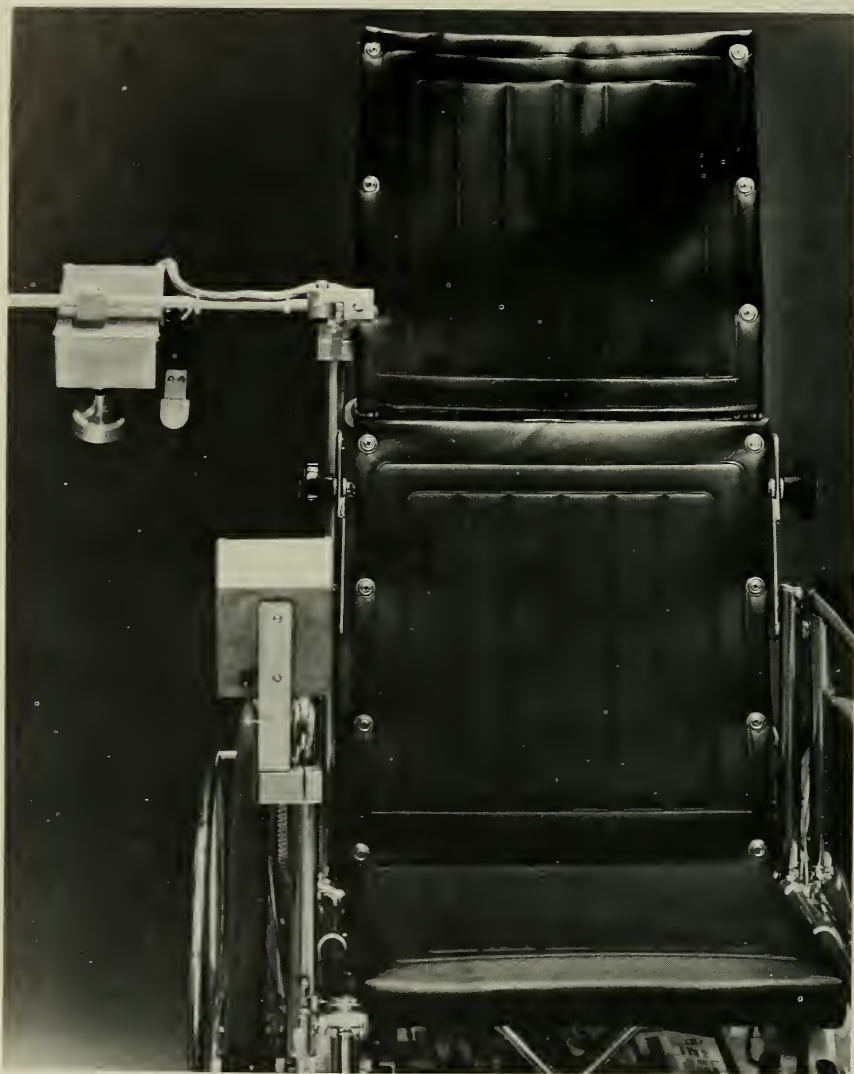
FIGURE 7.—VAPC Chin Control swivels to facilitate patient entry and exit.

A chin receptacle is attached to the proximal aspect of a proportional control joy stick. The Motorette or Everest & Jennings "33" Power Drive is readily adapted for use with this bracket. Indeed, both organizations are now producing the VAPC unit. It is interesting to note that many high level quadriplegics are usually able to use the chin control on high performance wheelchairs such as the E & J 24-volt system and the newly developed printed-motor power package.

For those patients who are unable to use either manual or chin control, two VAPC breath-operated systems are available. One has proved to be an extraordinarily reliable and generally useful system. Referred to as the VAPC Pneumatic Wheelchair Control Model II (Fig. 8), it incorporates two air tubes mounted on a small bracket in front of the patient's mouth. Constant blowing or sucking on either or both air tubes activates either or both motors to propel the chair or to change direction. Blowing into the air tube spins the motor in one direction while sucking on the tube reverses the motor's direction. The blowing or sucking generates positive or negative pressure, respectively, so that the occupant of the wheelchair is able to breathe normally. A speed control knob, mounted on top of the control section mounted in back of the wheelchair, may be adjusted for training purposes as well as for normal everyday use.

A second breath control design, the VAPC Pneumatic Wheelchair Control Model III, makes use of four air tubes (Fig. 9) and a unique switching arrangement that precludes the necessity for constant positive air pressure to propel the chair in the forward mode. Generation of a positive pressure pulse into the controlling air tube activates the wheelchair motor into a forward mode, which is maintained until a second puff of air is introduced into the air tube. As with the Model II design, two tubes are used to activate the drive motors. Generating negative pressure on the air tubes reverses the direction of both motors and is concluded when negative pressure ceases. A third tube permits the wheelchair occupant to vary his speed from 0 up to maximum. Generating constant positive pressure into the third air tube increases power to the motor while the chair is stationary or moving, and constant negative pressure reduces power to the motor. When the patient has achieved the desired power level, he ceases blowing into or sucking on the speed control tube and the selected power level is maintained. The fourth air tube activates a main power switch and an automatic reset circuit.

The Center's clinical introduction of these higher performing wheelchairs, especially those that accommodate the chin and breath controls, is generally considered to be contrary to standard and perhaps outdated rehabilitation medicine practice. Thus far, however, evidence is clear that VA patient demands for these devices are readily matched by clinical successes.

Our experiences to date suggest that we should direct our efforts to higher performing mobility aids. The upper limit of performance has not yet been defined, and so we tread forward in a most conservative manner. Our Center is presently engaged in the development of an intermediate or indoor/outdoor wheelchair (Fig. 10). We conceive this unit as being a higher performing vehicle primarily for outdoor use. But it must retain basic wheelchair characteristics and necessary physical size

and weight limitations to permit the vehicle to operate in the usual indoor environment.
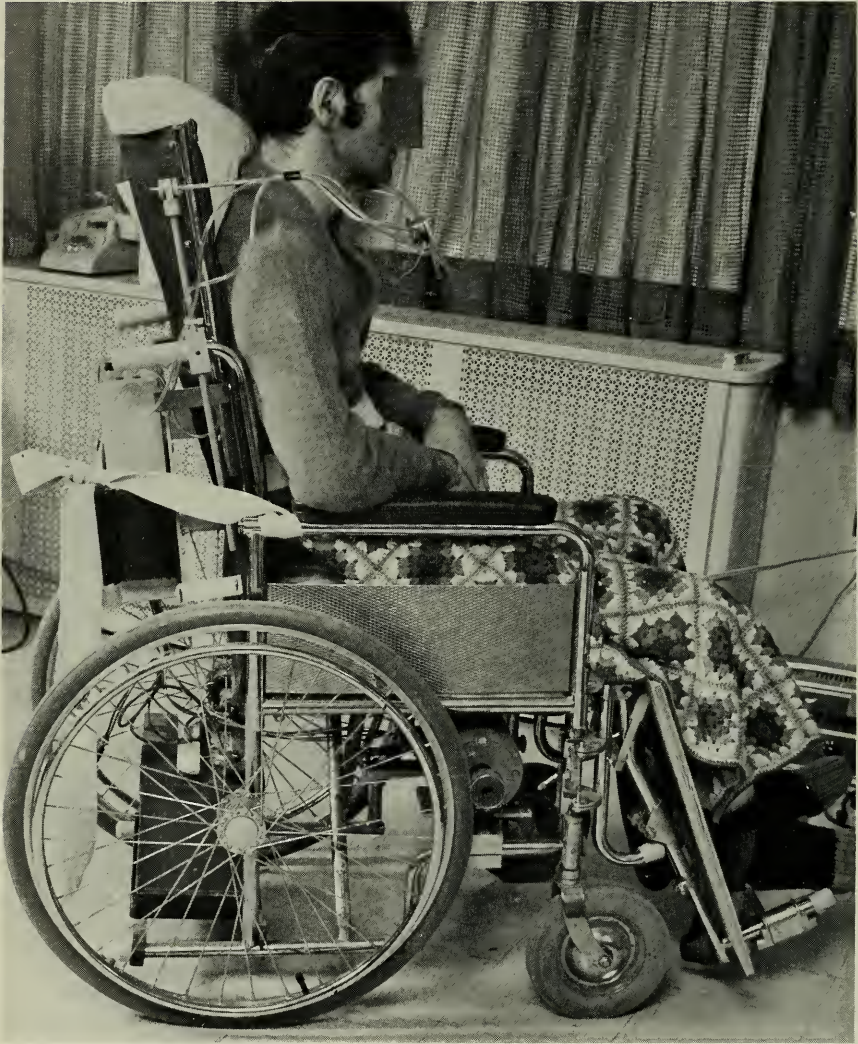
FIGURE 8.—VAPC pneumatic wheelchair control, Model II.

FIGURE 9.— VAPC pneumatic wheelchair control, Model IIĭ.

FIGURE 10.—Experimental indoor/outdoor powered wheelchair.

The VA Prosthetics Center enjoys a record of directing its efforts to apply the most recent technological innovations to the veteran beneficiary and, perhaps as important, is a stimulus to other development and manufacturing organizations to produce improved and less expensive varieties of nonlicensed mobility aids. We, therefore, anticipate that the civilian population will also benefit from our efforts.

VARIABLE-HEIGHT-POWERED WHEELCHAIR FOR THE QUADRIPLEGIC DRIVER

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FOREWORD

Originally the charge, under the SRS, was for us simply to improve on the mobility system for severely handicapped people. We interpreted this to include short-range travel, long-range travel, inside and outside, as well as horizontally and vertically. In short, any transport system which would help in daily activities, job execution, or recreation was to be considered. A few hundred man-hours were spent on preliminary design of an easily accessible special "automobile" which would accept a severely handicapped [a] person sitting in a standard powered (say E&J) wheelchair at driving position. Jerome Sills, a post-polio partial quadriplegic, was at that time (1967) driving a dropped-floor 1954 Ford Sunliner from a wheelchair. When it became obvious that a special wheelchair-compatible automobile would cost several times more than a standard automobile, this approach was discontinued. Assume that a standard auto costs $4,000, that the special auto, or greatly modified one, costs at least $10,000, and that the special auto is of little use to anyone other than the handicapped driver. This means that if we could somehow eliminate the need for the special auto — or its modification — we would have $6,000 to use for an alternate system. The obvious alternate system is a variable-height wheelchair which will fit in a standard automobile or van. A unit bid on these wheelchairs of $4,100, on the basis of three units, has just been received. This leaves $1,900 for some sort of lift or other entry system. A standard van-type tailgate lift costs under $500.

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[a] Ultimately a "severely handicapped" person was considered to be a C-5 quadriplegic.

More money (perhaps the full $1,900) would be needed for a lift for a standard auto. There appears to be no choice economically between going the special vehicle-standard wheelchair route as against the standard vehicle plus lift — special variable-height wheelchair route (note that the $10,000 cost estimate for the special auto may be low by 50 percent). However, when an appraisal of the tremendous expansion of daily activities possible through the exploitation of a variable (seat) height wheelchair is made, the choice is unequivocally in its favor. The possibility of a 17 in. increase in vertical reach — from 7 to 50 in. above the floor to 0 to 60 in. above the floor — is a very attractive (50 percent) one. This was the germination of the variable (seat) height wheelchair concept.

So attractive became the concept of mobility enhancement through variable wheelchair seat height that the VA asked us to push through the wheelchair, holding up development of the auto lift and driving equipment. Limited production of the wheelchair began in the fall of 1974.

HISTORY

Introduction

Prior to the initial funding of this project by SRS, Peter Bray wrote a survey thesis (1), which was published in part (2), wherein he outlined the mobility problems of severely handicapped people and also included a comprehensive state-of-the-art survey on quadriplegic functions, wheelchairs, vans, lifts, special autos, and hand controls. Mr. Bray (1) was also the first person to suggest a variable-height wheelchair.

The present UC wheelchair project was initiated by Peter Bray, C.W. Radcliffe, Biomechanics Laboratory; Jerome Sills, a post-polio partial quadriplegic, driving a 1954 Ford from a wheelchair; and D.M. Cunningham.

Special, Custom Designed Vehicles Accepting Standard Wheelchairs

In 1957, Jerome Sills supervised the modification of a 1954 two-door Ford Sunliner (1) to accept his junior manual wheelchair. He had the right front seat removed and the floor there lowered to 3 in. above the ground. He entered via the right front door by running his wheelchair up a 3 in 12 (14.5 deg.) ramp onto a turntable. Manually rotating the turntable placed him in right-hand driving position. Right-side steering wheel and hand controls enabled him to drive. Mr. Sills drove this vehicle for several years (until his death in 1970); he was fairly satisfied with it even though the structural integrity of the auto frame was in quesiton and the 3 in. ground clearance was unsafe.

In 1964, under the British Polio Fund, Mr. Leslie M. Ballamy (3) developed a system consisting of a manually adjustable height wheel-

chair and a high-roofed, tilting-floor vehicle. Using this system, a paraplegic could handcrank the wheelchair seat (with a force per stroke of 15 percent of body weight) from normal height down to a seat height of 10 in. The floor of this front-drive, Citroën suspensioned vehicle could be tipped back so that the rear tailgate (acting as a ramp) touched the ground. Easy rear entrance was possible — or side door entry — via a short ramp to the curb, by tipping the vehicle laterally. This was a good idea, but the expense of the body and suspension modification and the fact that paraplegics can normally transfer out of their wheelchair to an auto seat limit its application.

A short magazine article in 1966 made reference to a modified four-door Renault auto in which the top had been raised and the floor lowered for entry in a standard wheelchair. This is parallel to the Sills solution, except that between the years 1954 and 1966 auto top heights were lowered by 8 to 12 in., necessitating roof raising in addition to floor lowering. The trick here is to position the lap of a wheelchair occupant at a level just below the steering wheel. Again, this double modification is very expensive, reduces structural integrity, and spoils the esthetics of the vehicle.

About 1967, Mr. Fred Taberlet (4), a mechanic in southern California (now deceased), developed an unroofed front-wheel drive vehicle in which the whole inner floor from fire wall to rear and wheel to wheel could be lowered to the ground for wheelchair entrance. Although the auto was underpowered and the top remains unfinished, this vehicle was well adapted for drivers in standard wheelchairs.

On the UC project in 1968, Mr. David F. King conceptualized two 8-ft.-long, high-roofed, low-floored commuter-type vehicles for wheelchair-bound drivers: 1. a rear entry front-wheel drive vehicle and 2. a front entry (like the Isetta auto) rear-engined vehicle. The idea was to park at right angles to the curb with the entry end overhanging the curb — allowing ramp entrance. With wheels butting the curb, the extreme outer end of the vehicle was 7 ft. from the curb, which is probably legal. The expensive requirements of a completely customed body, special suspension, ramp extender, etc., precluded the development of these autos. Normal commuters might buy them — except for the awkward, high tops.

Standard Vans for Wheelchair Drivers

Many quadriplegics have adapted standard automatic-powered-step vans like the Metro (GM) 404 (1) for driving from an ordinary wheelchair by adding a tailgate lift, removing drivers seat, and covering up the standing step. This is a good solution. Not only is the cost of these vans comparable to a medium-priced automobile, but also the modification costs are minimal ($1,000–$3,000). The only disadvantages are the size,

height clearance in garages, awkwardness, and the question of future availablity of this type of van.

Alternatively, wheelchair-bound quadriplegics have decided on the newer Econoline (Ford), Dodge or Chevrolet vans. Each of these has the engine positioned forward and the right center, allowing a wheelchair space at the driving position. However, these vans have a relatively low top so that a full-sized person in a full-sized wheelchair has serious problems with head clearance and visibility. One partial solution is to build into the floor two sloping wheel wells which will drop the wheelchair 3½ in. (limited to this depth by the lower longitudinal wheelchair frame bars). This depth is insufficient for a medium-to-tall quadriplegic. Greater depression of the wheelchair has been acheived at Robin Aids (Vallejo, California) by building into the van floor a 26 in. × 48 in. elevator having a 10 in. vertical excursion. Although adequate, this is a very expensive scheme, and some types of vans have frame members in the way of the modification. A plus factor is the automatic collision restraint of the wheelchair by virtue of its containment in a "well."

Hand Controls for Auto or Van Driving

If the wheelchair is positioned correctly with respect to the steering wheel, most low-level quadriplegic occupants can drive with standard push (brake)-pull (accelerate) hand controls if the vehicle has power steering, power brakes, and automatic transmission. However, with an interfering wheelchair-vehicle interface, and/or with a high level (say, C-4—5) quadriplegic, a different driving control system is desired. Charles Scott (UCLA) has developed a small joy stick (like a Motorette unit) device for steering, braking, and accelerating, which can be mounted anywhere. Dr. Paul Newell (Texas A&M) is working on a related control system. Several American auto manufacturers have in prototype stage simple wrist twist (1) or pistol grip steering systems. All of the control systems mentioned have all switches located very near the steering unit, within easy reach. Volvo will market such an option in 1975.

Tailgate-Type Lifts for Vans

Several companies make standard lifts which can be rear- or side-mounted on a van. A 500-lb. capacity type is quite adequate for a powered wheelchair and heavy person. Standard units which fold flush outside the doors cost from $410 installed to $900 installed. Custom units which fold inside the doors when not in use cost $250 to $400 more, installed. In either type a small (4-6 in. long) ramp must be provided to allow the wheelchair to roll up over the thickness of the lift floor and a restraining lip provided which prevents the wheelchair from rolling off.

A loading ramp is another possibility, but unless the van floor is low

(e.g., Mercedes front drive) or the doors are next to a high curbing, a long (16–20 ft.) ramp is necessary to accommodate the 24 in. floor height (Table 1) and low wheelchair power.

TABLE 1.—*Size Comparison Between UC Wheelchair and a Standard E&J Wheelchair (with the same 5'8" person as in Fig. 1-9)*

Dimensions, in.	E&J[a] Premier 16" adult wheelchair seat ht. 18"	UC Wheelchair Configuration			
		Normal seat ht.[b]18" (Fig. 2)	Maximum seat ht.[b] 27" (Fig. 1)	Lowest seat ht.[b] 10" (Fig. 3)	Reclining backrest seat low (Fig. 4)
Overall length[c]	46.5	54.5	39.5	58.3	71.5
Overall width	23.3	24.5	21.0	24.5	24.5
Vertical clearance[b] (for a 6'0" tall person)	51.0 (53.0)	49.5 (51.5)	60.0 (62.0)	42.3 (44.3)	23.5 (23.5)

[a] Has overall dimensions comparable to the E&J power-drive chair.

[b] Seat heights measured from floor to the top rear of the 3 in. cushion.

[c] Extreme of frame, toes, head, etc.—as appropriate.

Automobile Lifts for Wheelchairs

There are several types of commercially available auto-mounted lifts (such as Hoyer or Trujillo) which allow paraplegics, or quadriplegics with an attendant, to lift themselves through the use of a sling out of their wheelchair into the front auto seat; the folding manual wheelchair can then be placed behind the front seat. No provision is made for handling a heavy, powered wheelchair.

Given the constraint of keeping the quadriplegic in the wheelchair seat while in the automobile, there would appear to be only two more viable possibilities: 1. have a Hoyer-type device lifting the seat and occupant separately from the wheelchair base or 2. lift the man and the whole wheelchair into the auto. At least half of the front seat of the auto would have been removed. In case 1. there still remains the problem of what to do with the wheelchair base — unless one was located at every destination. The case 2. solution would seem more expedient, however difficult. Considerations such as door height, head clearance, floor space, drive shaft tunnel, desirability for loading on curb side and driving from the left side, and interference between lift, wheelchair, person, and auto controls are some of the problems which must be overcome.

A partial scheme for auto loading of a manual wheelchair and occupant (5) consisted of an unpowered wheelchair with four 10-in. wheels or

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two 6-in. castor wheels and two 20-in. removable (locked on by two toggle clamps) rear wheels. Here the wheelchair is wheeled up to the left side of a small sedan (with its left front "bucket" seat removed). The paraplegic occupant manually pulls a hydraulic lift out of the auto which he connects to the right side of the wheelchair seat. Manually he pumps up the cylinder which lifts himself and the wheelchair free of the ground. If necessary (with the 20 in. rear wheels), he removes the chair rear wheels and places them in a special rack in front of the back seat. Now, he simply maneuvers his legs into the auto and manually rotates the pivoting arms of the lift and wheelchair into driving position. It is a very neat and compact package requiring no power source — a great solution for a paraplegic who does not want to transfer himself out of the wheelchair. It would be next to impossible to operate on a sloping street. This is not a solution for quadriplegics because it requires manually pumping the hydraulic unit and it will not accommodate a powered wheelchair.

The UC group has operated two auto-lift prototypes (6). One successfully placed a manual wheelchair into the right side (from the right ground position) of a 1967 two-door Corvair. Its disadvantages were: 1. a manual operation similar to Mühlemann's (5) was required for swinging wheelchair and unit into the auto (prohibitive on a side slope) and 2. the vertical clearance sacrificed (about 5 in.) by having the supporting tracks under the wheels (not the case with the Mühlemann solution) was prohibitive for a tall person. The other placed a crude variable-height-powered wheelchair in the driving position of a 1965 Ford two-door sedan, starting from the right ground side position. This was a bigger challenge but the lift had the same vertical clearance drawback as its predecessor.

A more recent approach at UC (6,7), overcomes all of the shortcomings of previous lifts. In this concept the UC variable-height wheelchair would be backed up to a two-door sedan with right door open and lift extended. Two forks on the lift would fully engage grooves under the wheelchair seat. "Lowering" of the wheelchair seat, since it was restrained by the forks, would cause all four wheels to retract upward about 10 in. A single control switch would actuate the powered lift mechanism which would program the wheelchair and occupant through the auto door, over the drive shaft tunnel, rotate the chair, and push it up into driving position. Alternately, the wheelchair could be programed into right-front passenger position. The original front seat of the auto would be removed, but no structural modifications of the vehicle would be necessary. Locking the wheelchair to the lift would provide accident safety. This automatic, programed lift is in limbo, at a point somewhat beyond the preliminary design stage.

Powered Wheelchairs

This is undoubtedly the broadest topic to be considered here. Even if we limit the discussion to 3- and 4-wheel, off-highway, single-occupant vehicles, the topic is very broad. At one end of the spectrum we have an almost completely paralyzed person driving a powered bed or guerney at 3 m.p.h. by mouth blowing, speech, or moving his eyes. At the other end of the spectrum we have an apparently normal person joy riding in a one-person golf cart-type tiller steering "wheelchair" at 45 m.p.h. Nearer the front of the spectrum is the low-level quadriplegic driving a modified battery-powered wheelchair via a joy stick control unit. No argument will be made to promote the use of wheelchairs. Clearly some handicapped people do need wheelchairs, until a better substitute comes along, and the number of people needing powered wheelchairs will probably increase as handicapped people age and/or their diseases (e.g., multiple sclerosis or muscular dystrophy) progress.

Only a cursory coverage of battery-powered wheelchairs will be given here. These are vehicles which can be used safely (and legally) inside any building, size permitting, as well as from a few blocks to a few miles outside on a relatively smooth surface (e.g., on a lawn, but not a plowed field). The d.c. motor, belt-driven, battery-operated system is completely self-contained on the wheelchair; periodic battery charging (usually daily) is required. A basic powered wheelchair is the E&J manual (originally folding) type to which has been added: 1. two rear-mounted permanent magnet (RAY) d.c. motors and 2. one or two 12-volt auto or golf cart batteries. The latter are larger but can be drained (discharged) to a lower voltage level many times more than a standard auto battery. Exotic batteries, such as nickel-cadmium, can be used, but they cost five times as much. Also included is a speed control and "steering" unit. A "joy stick" in forward position produces maximum forward speed using both motors at maximum speed; rearward position produces full speed in reverse; sideward stick motion runs one motor faster than the other, turning the wheelchair. A big advantage of this scheme is that the wheelchair can turn about its own axis. The seat is either stretched plastic or a board with a foam rubber cushion. Advanced Wheelchair, Stainless, Motorette, and many other companies, also make similar wheelchairs. Some have a more rugged nonfolding frame designed specifically for motor power. None of these provides for varying seat height, back reclining, feet retracting, or width narrowing.

Compass Industries and the E&J Mark 20 are examples of golf-cart type, single occupant, powered chairs. They can be set up for top speeds anywhere from 4 m.p.h. to 40 m.p.h. The low-speed version will climb a steeper grade than the high-speed version. Addition of a gear changer

increases hill climbing ability and/or speed range. Both of these wheelchairs (compared to the more conventional handicapped chair) are larger, heavier, more powerful, covered cosmetically, and have positive tiller steering and dynamic braking. Probably this oversized-tire type should be considered an outdoor but nonhighway-type vehicle. It is too large and bulky and has too large a turning radius for most inside uses.

Another outside-type vehicle is the Swedish Permobil (8). It has large (16 to 22 in.) pneumatic-tired wheels, enabling it to negotiate a plowed field or even a short course of 4 in. × 16 in. steps. The backrest reclines and leg rest extends independently. However, the seat is at a permanent 24 in. height and this vehicle is also large, heavy, and has a larger turning radius than the conventional wheelchair. It may possibly be a little over-designed, since it has seven actuators for the several mechanisms.

In the originality department, there is a paraplegic veteran at the VA hospital in Wichita, Kansas, who wheels his manual chair up to the side of an ordinary motorcycle, clamps the armrest to the motorcycle, and drives away at 25 m.p.h. through use of hand controls on the motorcycle (note: some motorcycles have the shift lever, as well as other controls, on the handle bars). This speed is extremely high for a conventional wheelchair.

Wheelchair Controls

The most widely used speed control system for powered wheelchairs, in conjunction with the joy stick forward, reverse, left, right unit, is the Motorette d.c. pulse-width-modulation unit. This solid state electronics unit sends longer and longer pulses to the d.c. motor as the joy stick is deflected. It is a smooth and very efficient unit.

Caster Wheels

The caster wheels used with the Motorette unit create some problems: 1. conventional caster wheels shimmy (wobble back and forth) at about 4-6 m.p.h. This can be minimized by a low friction "clamp" around the pivot axis but may crop up later as the clamping force decreases; 2. Casters are easily deflected as they go over an obstruction, such as a sidewalk edge and some time is required before the joy-stick system can correct the false path. A positive type, e.g., tiller or "steering wheel" type, would not have this limitation.

Positive Steering

Tiller-type steering is much more stable and safe, especially for speeds above 4 m.p.h., but the range of hand motion is too great for a quadriplegic to handle manually, say ±4 in., with the force that he can develop, say ±3 lb. Steering motors, one on each "castor" wheel, with electronic control, would solve this problem.

Reclining Wheelchairs

In any skin ulcer prevention program it is good to have a reclining backrest to shift the weight at least partially off of the buttocks. The Swedish Permobil (8) has a powered reclining backrest. Also, the Rugg (9) wheelchair, which is similar to the Permobil, has a reclining backrest. A group at Utah State University (10) has developed a versatile wheelchair (mobile platform) with a reclining backrest; it will recline at any position of the variable-height seat.

Supporting Surface

The buttocks of the human body were not evolved for sitting on—at least not for prolonged periods. When the whole body weight of a normal person is supported by the buttocks on a flat surface the mean pressure is about 25 mm. Hg. (11); maximum pressure (under the ischial tuberosities) is about 120 mm. Hg. (11). The average blood pressure in the arterioles is 70 mm. Hg. (14). Average pressure in the capillaries is 35 mm. Hg. (14) and only 15 mm. Hg. (14) in the small veins. So, even with an "optimum" cushion design (where we would have mean pressure (25 mm. Hg.) all over the bottom of buttocks and legs) there would still be a circulatory problem with venous return. Any design allowing a pressure buildup anywhere greater than 35 mm. Hg. would greatly reduce blood supply. Limiting the blood supply, plus such factors as traction on the skin, local humidity, or skin temperature buildup, will tend to kill the skin and underlying tissue. Clearly, any "cushion" other than the perfect one causes pressure which cannot be sustained long. Even the optimum one causes problems.

To date, in order to guarantee the prevention of decubitus skin ulcers with any seat cushion, the buttocks pressure must be relieved periodically. Quadriplegics in wheelchairs are trained to do "pushups" by lifting up their upper body with elbows on the armrests or by leaning as far forward (head to knees) as possible with elbows looped through straps connected to the backrest. Another viable solution, which has other advantages, is the reclining back arrangement of some wheelchairs. A reclining back not only reduces the net buttocks pressure by an acceptable factor of 1/3 to 1/5, but this action, as well as that of an articulating footrest, maintains some of the tone desired in the paralyzed muscles (e.g., reclining the wheelchair backrest and leg rest periodically is a substitute for "range of motion" exercises necessary to keep joints from stiffening).

Variable-Seat-Height Wheelchairs

A group of engineers at the University of Utah (10) have developed a "mobile platform" which has a seat that can be raised from normal (18

in.) height to table height, where the backrest can be reclined for transferring to guerney or operating table. It is a good device for hospitals but would be limited in daily activities for lack of a second (lead-acid) battery and the need for a lower seat height for van transport and reaching a hand to the floor.

The Motorette Corporation has recently marketed a small, highly maneuverable Capp Cart (15) wheelchair with a seat capable of being elevated from normal (19 in.) to a 27-in. maximum. All wheels are 8 in. in diameter with solid rubber tires, limiting the wheelchair to smooth surfaces and low speeds. No footrests are included since the chair was designed for limbless (e.g., thalidomide) children. These could be added, however. It also has only one lead-acid battery, which limits its range. Mr. James Allen of Wheelchairs, Inc., has developed a similar variable-seat-height wheelchair (16). An important modification, consisting of an articulated footrest, was added to this by Mr. Charles Scott of UCLA.

All three of these variable-seat-height wheelchairs have the same drawback: the lowest seat position is limited to about ordinary chair height because the ball screw or hydraulic lifter is located in a vertical position under the seat. It would be very desirable for the seat to go down another 8–10 in. so that the occupant could reach the floor with one hand and fit into a low van or automobile while in the wheelchair.

Curb-and Stair-Climbing Devices

Possibly the greatest architectural barriers to wheelchairs are stairs and curbs. Even with the aid of one or two attendants, carrying a person in a powered wheelchair up several building stories is impractical, if not impossible. Lifting the wheelchair over a curbing is hard enough. In most residential areas there are enough driveways per block to enable a wheelchair user to traverse from sidewalk to sidewalk without going over a curbing. In many downtown areas there are no driveways and the convenient curb ramps for wheelchairs have not been put in. Unfortunately, the heavier the wheelchair (and occupant), the more desirable it is to have a curb ramp (or nearby driveway) or a curb-climbing device on the wheelchair. Present curb climbers or concepts are awkward, heavy and expensive, but can be made relatively safe to use. Conceptual stair climbers, on order of magnitude, are complicated (12), particularly if all sizes of stair risers and length of runs are to be accommodated. Stair-climbing safety is another matter; a failure or slip at the top of a stair run could be catastrophic. A limited solution for a given stairway is the personal elevator; transfer from wheelchair to "elevator" is a severe problem and the empty wheelchair must somehow be gotten up the stairs (or two chairs used). For the most part wheelchair users, without access to ramps or regular elevators, are confined to the first floor.

Wheelchair Transfer

One of the biggest problems of a quadriplegic is transferring into and out of a wheelchair to bed, toilet or toilet chair, bath tub, guerney, or any other sitting or lying appliance. The problem is minimized for a small- to medium-sized handicapped person with one attendant. A large person has a much greater problem and may need two attendants on occasion. Various Hoyer-type cranes or mechanical aids can partially replace attendants. Ideally the transfers can be made with a minimum of assistance—except possibly some passive overhead hooks, straps, or ropes.

Since the safest transfer path is sideways from the wheelchair, even for "falling" out of or into the wheelchair, no obstructions should prevent themselves in this path, either on the wheelchair or appliance transferred to. It would be of great assistance if the seat of the wheelchair could be raised to a level somewhat higher than the surface being transferred to and vice-versa.

THE UNIVERSITY OF CALIFORNIA
VARIABLE-HEIGHT WHEELCHAIR

Background Steps

1. The concept of a specially designed custom-made vehicle which would accommodate a conventional wheelchair and occupant, as driver or rider, was rejected as being:
a. Too expensive.
b. High (over 6 ft.) and awkward.
c. Having no other function (not useful for nonhandicapped people).
2. A lift concept for placing the variable-height wheelchair and occupant into a standard American two-door sedan was deferred until the UC wheelchair went into the production phase.
3. A curb-climbing wheelchair concept was deferred as having a lower priority than other daily activities.
4. All efforts were directed toward finishing the UC powered, reclineable, adjustable-height, and narrowing (PRAHN) wheelchair, with the design emphasis on daily activities in the home, work place, recreation area, going short distances on relatively hard smooth surface outdoors, and transporting wheelchair and the quadriplegic in a standard van with ample head clearance, good visibility, and good driving capability.

Design Constraints for the UC Daily Activities PRAHN Wheelchair

1. It must be *no larger than a conventional manual wheelchair* with minimum weight compatible with the listed functions.
2. It must have *maximum possible continuous variation in seat height* limited

only on the low end by the height of the batteries under the seat and at the high end by the greatest extension of the seat supporting mechanism. Elevating actuator must be self-locking.

3. It must *present no lateral obstructions to body transfer* on either side for as much of the seat height range as possible.

4. It must have *adequate speed*, grade-climbing capacity, and adequate acceleration.

5. It must have the *maximum possible battery range* compatible with other constraints.

6. It must have a *minimum turning radius*.

7. It must be as *stable as possible* at all heights (e.g., have an optimum center of gravity location and/or motor acceleration and speed limiter at the high seat heights).

8. It must be capable of *passing through a public toilet stall door*.

9. It must, incidentally, *give the occupant maximum vertical mobility* or reach (e.g., from the floor (without leaning over) to light switches, wall phones, above-sink cabinet shelf, etc.).

10. It must allow the closest possible *frontal approach* to a vertical wall.

11. It must *fully extend legs and back* (e.g., recline) in at least one position for resting and relief of buttocks pressure.

12. It *must be durable and trouble-free.*

13. It must be *compatible* in size, maneuverability, head clearance, and visibility *with the standard "Big Three" vans* and the checker sedan. (These are the modern vehicles, like Ford Econoline, with windows all around, side and rear doors, flat floor, power equipment, and automatic transmission. In the vans the engine is situated in front, forward, and 6 in. to· the right of center. The latter arrangement allows positioning the variable-height wheelchair at the steering wheel.

14. It must be *adjustable in size* to 90 percent of the adult population.

15. Clearly, the overriding consideration is that, if the UC wheelchair is to be accepted by a large segment of the physically handicapped population, it must provide for superior performance in the area of *daily activities*.

16. Stated another way, this wheelchair would be one in which a handicapped person could *sit during most of his waking hours*. So it would be used inside the home, office (or other work place), for recreation, and limited outside (on sidewalk or road shoulder) travel. Long distance travel would hopefully be accomplished with the handicapped person sitting in the UC wheelchair placed in a van in driving or passenger position or in an airplane, train, or ship.

17. *Wheels*

    a. Front wheels must be caster (for two-motor, tank-type push) types of 8 in. diameter or less, in order to clear the batteries and linkage with the seat low.

b. Rear wheels must be 16 in. in diameter or less in order to clear the armrest with the seat low (Fig. 3) and for unobstructed lateral transfer.

18. *A minimum number of actuators* would carry out all mechanical functions except for propulsion.

19. The basic seat-leg rest must be securely *clamped to the transport vehicle,* and the occupant strapped to the seat or to the floor. This restraint system must withstand a 20 g impact loading (front to rear).

20. The raising-lowering mechanism should have *pseudo pivots* at the occupant's knee and hip joints to prevent any pulling or bunching of the clothing during seat raising or back reclining.

21. *Standard,* commercially vehicle, durable *parts* should be used as much as possible.

GEOMETRIC AND FUNCTIONAL DESCRIPTION OF MARK IV (1974) UC POWERED VARIABLE-HEIGHT WHEELCHAIR (PRAHN)

A first impression of the UC wheelchair is that it is conventional in many respects (Fig. 1–9). It has four wheels—two small castors in front and two larger individually-driven rear wheels. A standard Motorette pulse-width-modulation, joy stick speed control and "steering" unit is used. The chair itself has a flat, cushioned seat and a separate, curved metal backrest. In other respects the UC wheelchair is nonconventional in that it is powered, reclinable, adjustable-height and narrowing, hence the acronym PRAHN. When the seat of the wheelchair goes up, everything else moves in: the footrest moves back under the seat and the tread (front and back) narrows. When the seat moves down the reverse occurs (tread widens and footrest extends) until finally, at the bottom of seat travel, the backrest reclines. One ball screw actuator does all of this. An unconventional bevel gear device unit is used for positive drive and because of the great restriction on the places and orientations where the drive motors could be situated.

A detailed description of the UC wheelchair follows. This is organized so as to indicate item-by-item how the design constraints were satisfied.

1. *Dimensions and weight:* Pertinent dimensions of the UC wheelchair in the various configurations are given in Table 1 where they are compared to those of a standard E&J wheelchair. For comparison, some related van and Checker Auto dimensions are given in Table 2. Notice that a 6 ft. person in the conventional E&J wheelchair would barely clear the van ceiling when inside, would have to cock his head greatly to clear any van door, and could barely see under the top of the windshield (eye level is 5 in. below seated head height). The 21 in. × 39.5 in. vertical projection of the UC chair at maximum seat height allows turning around in a 40 in.

hallway and a standard 22 in. wide toilet stall door can be entered easily. Any horizontal barrier 24 in. or more high can be passed under with the backrest reclined. Wheel choices. besides these being commercially available and rugged. were based on the fact that "standard" 8 in. castors were the largest possible which would pivot 360 deg. at all seat heights and clear the mechanism. and the 1¾ in. × 16 in. pneumatic Sting-Ray bicycle wheels have some cushioning properties and are the largest possible for easy. unobstructed lateral transfer at normal (and above) seat height (Fig. 2) and they allow unobstructed lateral arm (elbow) movement (Fig. 3 and 4) at all seat heights. The seat cushion width is 16.5 in. The inside dimension between armrests is 17 in.; 2 in. can be added if an attendant simply removes the armrests (two bolts) and interchanges them. The penalty for the latter adjustment would be that the overall width range would now vary from 25 to 23 in. (25 in. to 21 in. before). Ninety-five percent of the population can be accommodated through the adjustable single-center-post footrest. Variations in individual thigh lengths are taken care of by moving the lower end of the sliding seatback forward and back. The headrest. essential for reclining and preventing automobile whip lash. will be universally adjustable. Swing-away armrests have up-down and inclination adjustment mechanisms. The weight of the wheelchair shown in the figures is 256 lb. Anticipated minor modifications will not change the weight appreciably.

TABLE 2—*"Big Three" 1973 Van Dimensions* (inches)

	Chevy 110	Ford E 100	Dodge B 100	Checker Sedan (Flat Floor)
Floor-Windshield top (visibility)	47.0	46.4	47.0	43.0
Maximum inside height	53.8	53.4	53.2	44.8
Rear door opening height	48.8	47.4	47.2	—
Side door opening height	49.2	47.4	47.2	42.8
Overall height	80.0	76.0	80.8	62.8
Floor height	25.0	22.0	27.0	14.5

FIGURE 1.—UC wheelchair at maximum (27 in.) seat height with feet retracted.

FIGURE 2.—Normal seat height, legs partially extended. Lateral transfer is unobstructed across rear wheel fender when swing-away armrest is up.
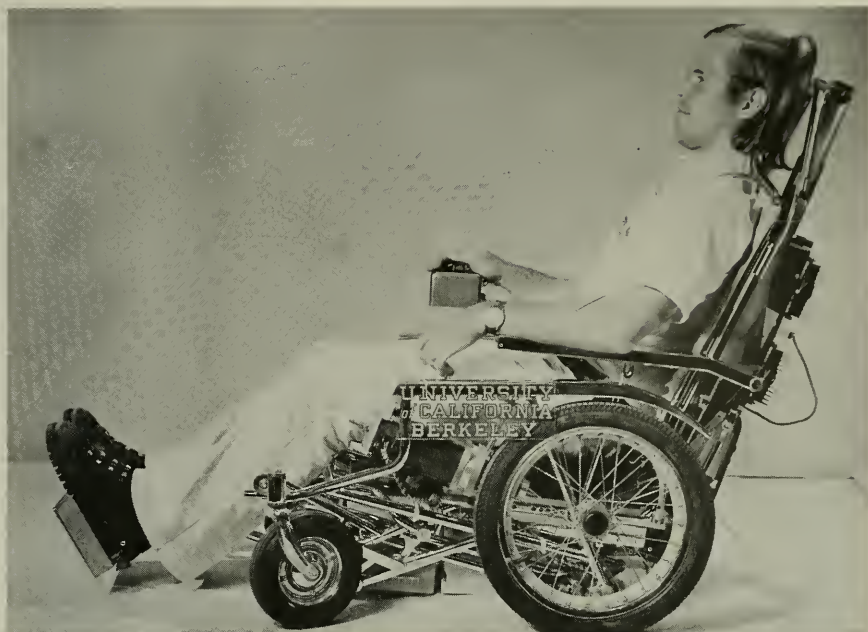
FIGURE 3.—Lowest seat height (10 in.). A lower seat height (7 in. minimum) is possible if smaller batteries are used.
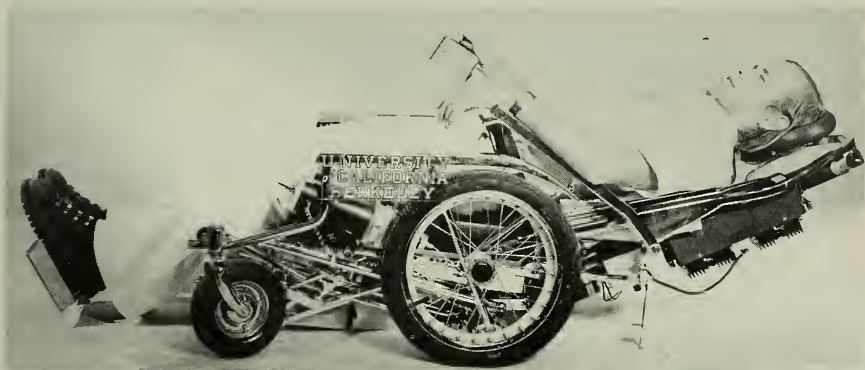
FIGURE 4.—Continued shortening of the single actuator brings the backrest down with the seat and legs in the low (see Fig. 3) position.
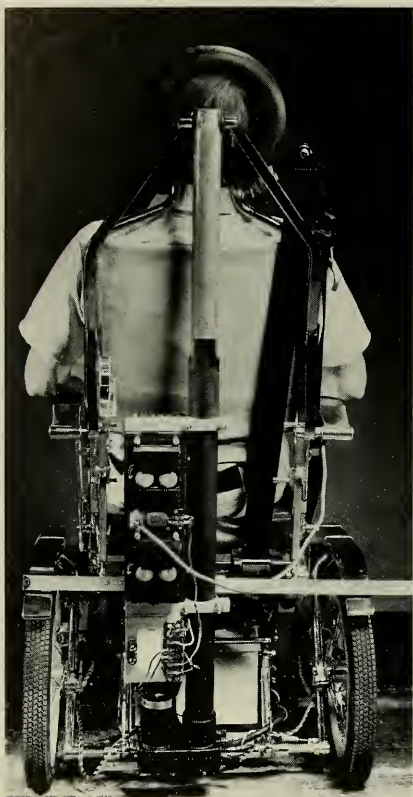
FIGURE 5. — When seat is at normal height (or lower) the overall width is 25 in. Note rear-mounted, central, single actuator, and attached speed control unit (for wheel motors).
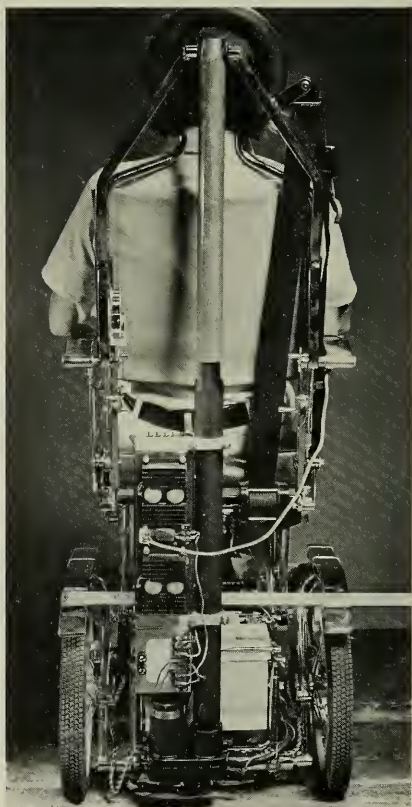
FIGURE 6. — As the seat goes up, the overall width reduces to 21 in. for easy entry through legal-sized toilet stall doors.
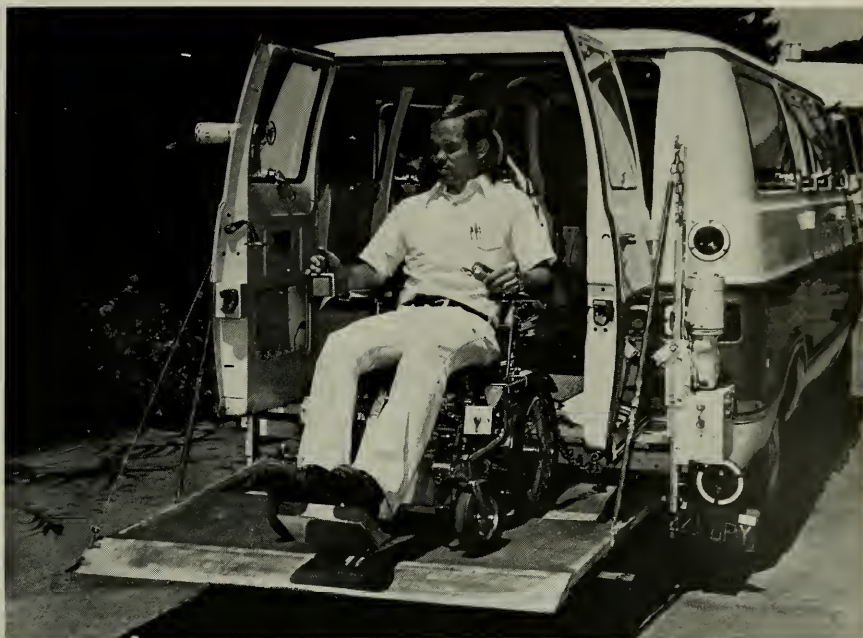
FIGURE 7.—Subject in UC wheelchair entering a Chevy van via a commercial tailgate lift.
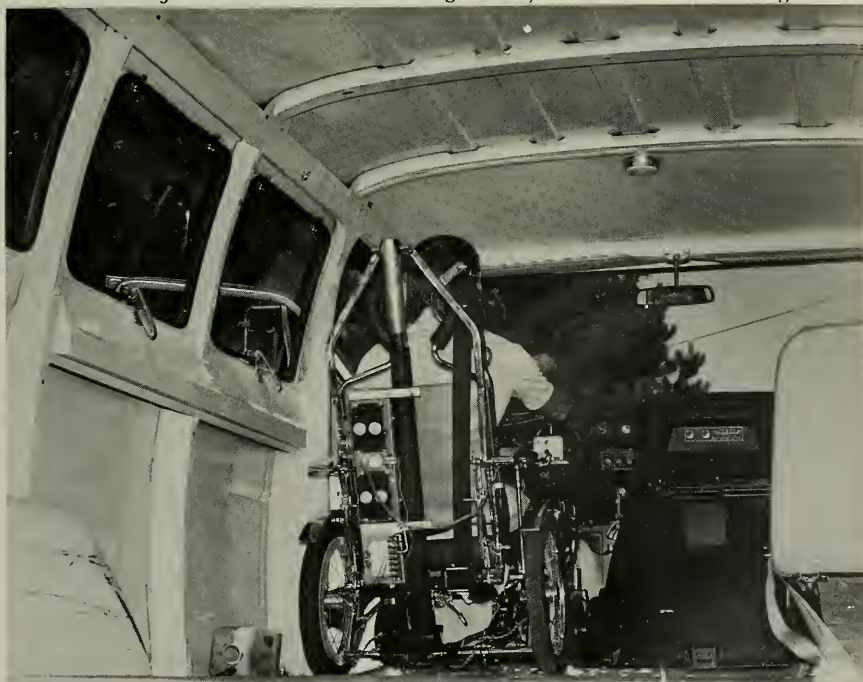
FIGURE 8.—UC wheelchair in driving position in Chevy van. The seat is low, giving ample head clearance and visibility without wheel wells (subject height: 5 ft. 8 in.).

FIGURE 9.—Demonstration of head clearance, visibility, and driving controls access for a person of average height. The wheelchair seat will lower another 6 in. for a taller person.

2. *Height range:* A seat height range (Fig. 1-3) from 10 to 27 in. is possible and the ball-screw actuator automatically locks at any seat height — eliminating the need for a braking device. Limit switches control its range. The inclination of the lower seat surface stays continually at 7 deg. to the horizontal from maximum height to minimum height. The absolute minimum of the seat height (now 10 in.) could be reduced to 7 in. if the batteries were removed or replaced by more compact ones, such as the "dry" GEL-CELL types with an optimum configuration. Note that the wheelchair can be driven, with full castoring capability, at any seat height or with the back reclined.

3. *Obstruction-free transfer:* The most difficult part in designing the height-varying mechanism was to locate it entirely under the seat and beside the two auto batteries; the prime object being to keep the wheelchair compact and have no obstruction to lateral transfer in and out of the chair. There are no lateral obstructions for seat heights from 18 to 24 in.

4. *Speed:* The UC wheelchair carrying a 180 lb. person will climb a 6 percent grade at 3 m.p.h., using the two Ray motors and Motorette speed control unit. A steady level surface speed of 7 m.p.h. can be attained. Acceleration is quite adquate.

5. *Battery range and life:* These quantities have not been measured yet. Life and range should be as good as an E&J wheelchair with belt drive, Motorette with tire-friction drive, and Advanced with a chain drive, if, in each case two comparable auto batteries are used. Two large capacity golf-cart batteries will not fit. The wheelchair could be modified to accept a single golf-cart battery with the penalty that the lowest seat position would increase from 10 to 14 in.

6. *Maneuverability:* This feature is felt to be quite adequate, since the dimensions of the chair are minimal and it will turn about on its own axis. A 40-in.-wide hallway, or equivalent is sufficient space. Also, the Motorette unit gives smooth control and variable acceleration, which is essential for moving about quickly and positively in tight quarters.

7. *Stability:* It is a serious challenge to try and make the UC wheelchair dynamically stable when the seat is high, frame narrowed, and footrest pulled in. Anyone can produce a "wheelie" (front wheels leaving the floor) with the seat high at maximum acceleration (joy stick forward) from a standing start. Obviously, on a steep incline with the seat high, it would be easy to overturn the wheelchair. Since the wheelchair is very stable and safe with the seat low, an electronic device, which will limit acceleration and top speed as a function of seat height, will be added. No penalty in performance will be paid because the high seat position will only be used for reaching up high or maneuvering in tight spaces.

8. *Narrow passage:* The present prototype will pass through 25-in.-wide openings at all seat heights; at maximum seat height (or up to ½ in. lower) it will pass through a 21-in. opening, and turn around in a 40-in. hallway.

9. *Vertical mobility:* With the quadriplegic occupant strapped in or with one elbow looped through either side backrest handle, he will be able to reach the floor with one hand by leaning slightly to one side (Fig. 10). The maximum height reachable depends upon available arm function but it would be at least 9 in. higher than possible with a standard 18-in. seat height. Then wall telephones, light switches, above-sink shelves are accessible. In high position, the quadriplegic has the same head height as a 5-ft. person (Table 1), so he can be almost at eye level with a normal standing person for conversation, speech making, and sports; a great psychological boon. The chronic problem of adapting standard wheelchairs to varying desk, table, and bench heights (by armrest cut outs or complete removal) is met by the universality of vertical height adjustment. Finally, the quadriplegic can see out of windows and over surfaces inaccessible to him before.

10. *Frontal vertical surface access:* Since the footrest of the UC chair retracts in high-seat position to a point where the toes are behind the front of the fixed frame and castor wheels, it is possible to make a very close approach within 3 in. of the knees (Fig. 1) to a vertical surface. In

FIGURE 10.—A minimum of leaning is necessary for reaching objects on the floor with the seat low (Fig. 3 configuration).

conventional wheelchairs (or the UC chair in a lower seat position) every vertical surface must be approached tangentially from the side in order to reach it with the hands (arms extended).

11. *Reclining:* A no-cost feature of the UC chair is the full reclining of the backrest when the seat is low and legs extended. Not only will this be helpful in redistributing pressure on the buttocks, but also it allows resting while in the wheelchair and passage under 24-in. horizontal barriers. Unfortunately, reclining is not possible at other seat heights (e.g. for guerney-to-table-type transfer) but, again, no price was paid for the present reclining feature—continuous shortening of the actuator, with seat low, simply pulls the backrest down.

12. *Life expectancy:* Life tests on the UC wheelchair are yet to be carried out. Daily activities testing on three VA-funded prototypes will begin in late 1974. Long life is expected because redundancy in the linkage assembly has been completely avoided; ball or RULON bearings have been used in all moving pivots or sliders; parts have been sized to take a 50 percent overstress; and all frame members have been protected by chrome plating. The Berkeley prototype has been operated intermittently every day for several months, with many battery charges.

13. *Van compatibility:* It is possible for a 6-ft. person to enter, see out of, and drive a conventional van or Checker sedan while seated in the UC wheelchair. No modifications of the van are necessary except to cover

the step area next to the left front door and to provide access via a ramp or "tailgate" lift (compare dimensions in Tables 1 and 2). Even in the smallest (Dodge) van a 6-ft.-high man in the UC wheelchair in low position can enter either door with 3 in. of head clearance, sit inside with 9 in. of clearance, and drive with 8 in. of vertical eye clearance (eye distance below top of windshield). This means that either a 6-ft. 6-in. man would be accommodated or the 6-ft. man could move the seat up from 3 to 6 in. for better steering wheel reach, etc.

Of interest is the fact that an average (or slightly higher) height person in the UC chair down low can fit through the door of a standard Checker sedan or station wagon and sit comfortably inside at, say, driving position with acceptable visibility. Inclining the backrest slightly more would improve visibility. Having a floor height of from 7.5 to 12.5 in. less than the van's, expedites wheelchair entry.

Quadriplegics in standard wheelchairs seem to be opting for Chevy vans (Fig. 7–9), probably because all clearances are greater than in the other two (Table 2). We, having a less critical clearance limitation, would choose the Ford van because of its more accessible (lower) floor.

Parenthetically, the UC wheelchair was originally designed to fit in driving position in a standard-sized 1974 Dodge (Plymouth), Ford or Chevy, or bigger two-door sedan. Obviously, as suggested above, there would be a head clearance and visibility problem. Since the UC wheelchair seat will go down another 3 in. (to 7 in. off floor) with batteries removed or reshaped (e.g., use small Gel-Cell types), this will suffice, except for very tall people.

14. *Fitting the population:* The UC wheelchair seat system will adjust for the 5th through 95th percentile in body size. The modes of adjustment are:

    a. length of thigh
    b. height of elbow above seat
    c. angle of armrest
    d. body width
    e. height of head above seat
    f. pillow height (fore-aft headrest position)
    g. headrest angle (against back of head)
    h. angle of backrest from vertical

The chair is adjusted to a new user as follows (Fig. 11):

First, the backbrace (Fig. 11, item 6) is set at approximately the right angle by turning the turnbuckles (item 22). The seat is run to a height such that the shank of the footrest is vertical. The user is positioned on the seat such that his lower legs are also vertical. (The thigh length adjusting link mounting screws (item 46) must be removed to allow the backrest (item 7) to swing to the correct position). The backrest is positioned to support the user comfortably, and the link mounting screw

(item 46) is inserted and tightened in the most appropriate hole in the seat plate (item 4). Now the backbrace angle can be reset if necessary
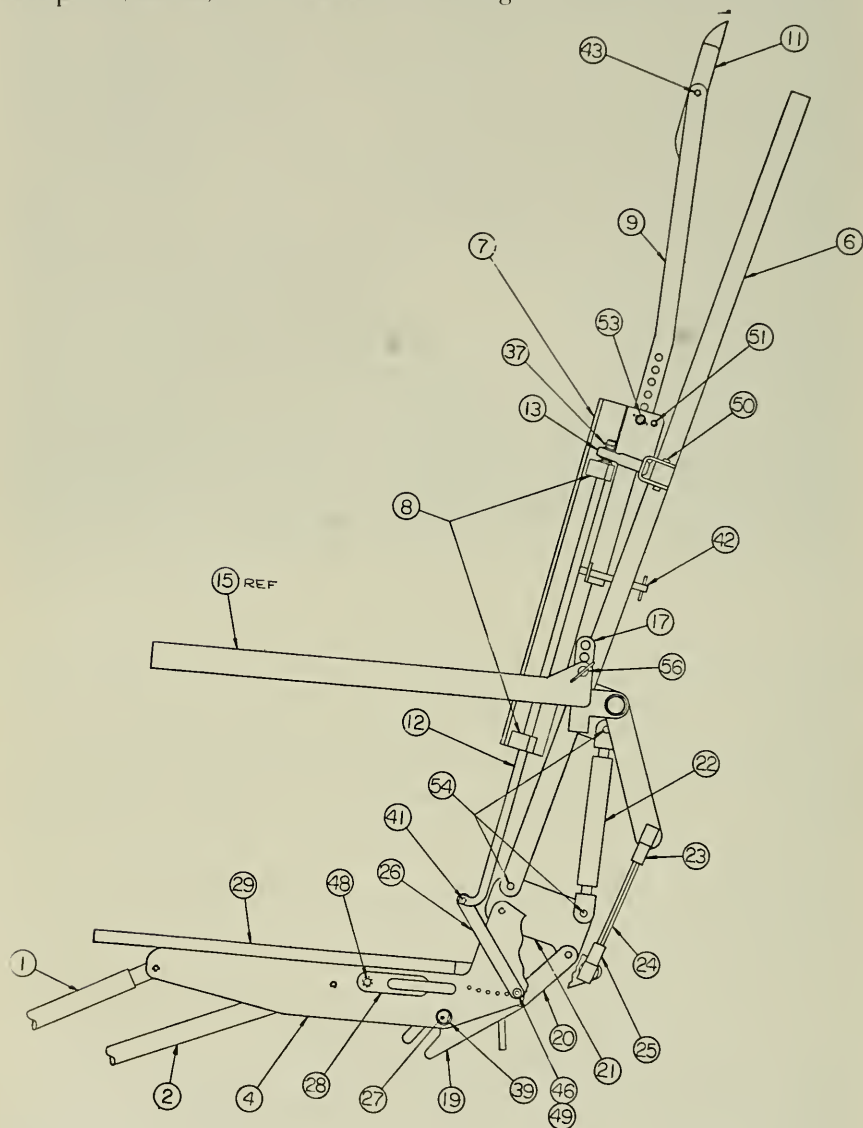
FIGURE 11.—Assembly drawing of the new seat, backbrace, pivot, and recline system.

Next, the armrest (item 15) is set at the correct height by removing the mounting pin (item 56), positioning the armrest, and reinserting the pin in the correct hole. For a person with a wide torso, the offset armrests can be switched side to side to allow an extra 2 in. of width. The armrest

angles can then be adjusted by rotating their respective turnbuckles (item 24).

Finally, the headrest must be positioned. First, the height is set by pulling the pins (item 53), moving the headrest to the desired position, then reinserting the pins. (Both sides must be done at once.) The "pillow height" is then set using the adjusting screw (item 42) at the bottom of each headrest support (item 9). Finally, the headrest angle is set by loosening the mounting screws (item 43), positioning the headrest, and retightening the screws.

15. *Daily activities performance:* Hopefully, the potential user of the wheelchair will be convinced by reading about functions 1 through 14 that this wheelchair will excel in daily activities use. Certainly the three quadriplegics who have briefly tried the UC wheelchair were enthusiastic. Further trial information will be available after the VA sponsors the construction and "field" testing (at VA Spinal Cord Injury Centers) of three prototypes during 1975. These tests will emphasize daily activities more than vehicle driving.

16. *A single wheelchair for everything but sleeping?:* Only time will tell whether a quadriplegic can do virtually everything while in only the UC wheelchair. It is well known that many severely handicapped persons have several wheelchairs: one for inside the home, one for outside, one for sports, one for airplane travel, etc. The practicability of a universal-function, powered wheelchair has yet to be tested.

17. *Wheels:* The 8 in. front castor wheels allow for reversing or sharp turning at all seat heights (e.g., at no time do they interfere with the mechanism or frame). Also, the 16 in. rear wheels are small enough to allow ample hand, forearm, and elbow freedom at all seat heights, as well as unobstructed transfer across the fender at normal chair height. The 1½ in. wide semi-pneumatic tires are adequate for the front casters. The 1¾ in. wide pneumatic rear tires are still better from a weight and cushioning standpoint. Wider tires would simply take up too much space.

18. *Actuators:* There is only one actuator for moving the mechanism. This single actuator: a. varies the seat height, b. retracts the leg rests, c. narrows the tread, and d. reclines the backrest. The Swedish Permobil has seven actuators. A disadvantage of having only one actuator is not being able to move each mechanism separately.

19. *Safety restraints:* A Volvo (aircraft type) inertia-reel, over-shoulder seat belt is provided to strap the quadriplegic securely to the wheelchair seat, yet give him freedom of arm motion (if he is capable of any). When he is a passenger in or driver of a van-type vehicle, the wheelchair seat will, in turn, be securely fastened to the floor of the van. Clamping will be done by the wheelchair elevating mechanism as follows: the wheelchair, with seat 2 in. above minimum height, moves forward until a locking pin

(Fig. 12) on each side of the backrest pivoting mechanism hits the vertical surface of a strong floor-mounted bracket. Lowering the seat height by 2 in. drops each locking pin into a bracket hole. Further seat lowering pivots the backrest forward 5 deg. and back again, rotates locking pin 35 deg. and lifts rear wheels ½ in. off the floor. Continued reclining of the seatback rotates locking pins still more—to a maximum of 100 deg. All the while, the wheelchair is restrained in all directions. Locking pin, wheelchair seat and occupant can withstand a 20 g frontal acceleration.
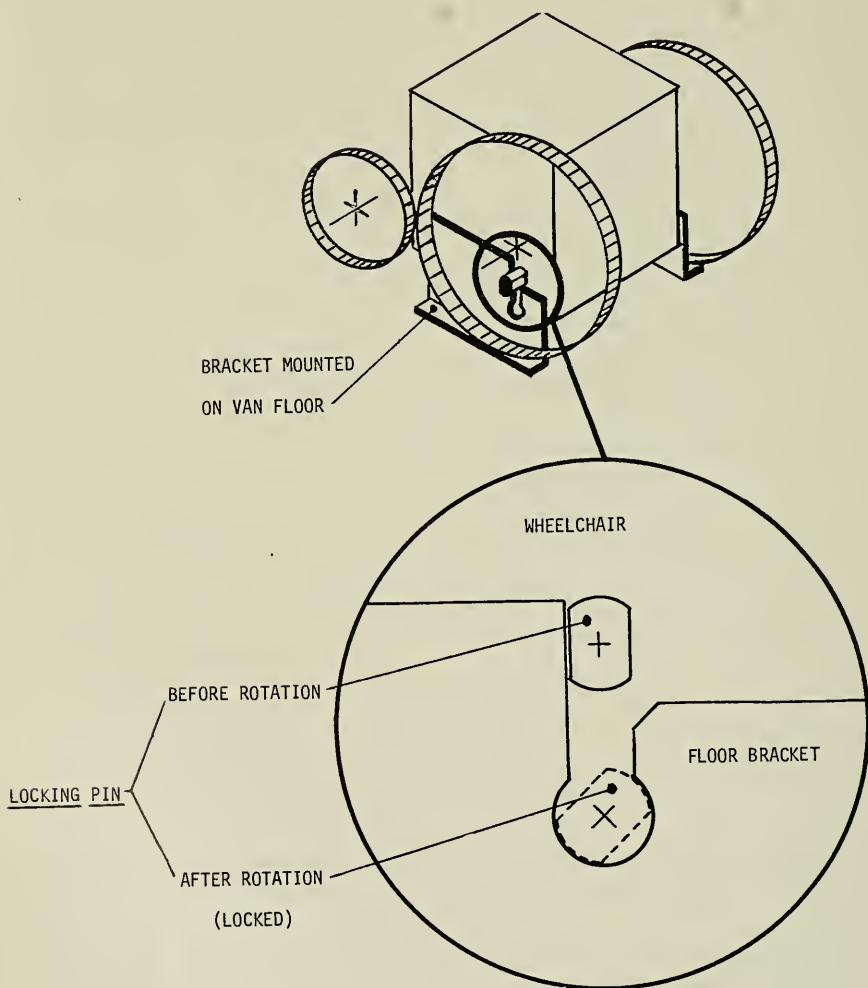
FIGURE 12.—Sketch of UC wheelchair van lock-down mechanism.

20. *Natural pivoting:* Traction, shearing, pulling, tearing, bunching, or shifting of clothing (or supporting skin) is prevented by the expedient of having the leg-extending mechanism "pivot" set at the anatomical knee joint and using a sliding backrest to accommodate a moving hip pivot. Note (Fig. 3 and 4) that reclining the backrest has shifted the head rest (and seat-back) 3 in. relative to the top of the actuator.

21. *Standardization:* Readily available materials and components are used as much as possible. For example, all frame chassis and mechanism parts are made of cold-rolled steel — mostly round and square tubing. The only heat-treated parts came that way, such as some machine screws, the transverse tube (lowest cross-member in Fig. 5), ball bearings in rod ends on links, wheels, motors, and actuator. The ball-screw actuator and motor is a standard (Saginaw) 24-in. stroke unit. Batteries are a standard VW (#2YW-111-645) and a Sears (#4310). The many ball bearings are stock items, the linear bearings are RULON (derivative of Teflon) sleeves. There are some exotic parts, such as the handmade nylon bevel gear (visible just inside the rear wheel rim in Fig. 1-4), and curved, tapered fenders.

DISCUSSION

Many compromises were necessary in the development of the UC PRAHN (powered, reclinable, adjustable-height, and narrowing) wheelchair. One such was the undesirable limitation on the lowest seat position caused by placing two lead-acid batteries under the seat (placing these batteries anywhere else would either make the wheelchair unacceptably large or top heavy). Another compromise was choosing a linkage which would limit the maximum seat height to 27 in. (another linkage might have provided greater height but would not lower the seat as much and would be bulkier or weaker). A third compromise was to reject the use of a linkage which would place seat-backrest "hip" pivot at the anatomical hip pivot (this would have precluded the van lock-down feature and also added greatly to the complexity). Instead, the sliding backrest expedient was used. A fourth "compromise" was to use swing-away, interchangeable arm rests, rather than detachable (or other type). This allows running the wiring for switches and joy stick through either armrest. There are several simplifying compromises where two or more functions were designed into one mechanism. The prime example is the use of a single actuator where four might have been used (if they would fit). The use of castor wheels and push-pull steering, along with the Motorette pulse-width-modulation unit, is a conventional compromise. Castor wheels must be damped to prevent shimmy and when they are deflected by a bump, rock, sidewalk edge, etc., it takes appreciable time to correct the wheelchair path with the joy stick control. Positive (like a

modified tiller type) steering is better and safer but more complicated and, hence, expensive. At this date, the new compact Motorette control unit is felt to be the best of those commercially available. A perhaps temporary compromise was to omit a battery charger, in the interest of simplicity and reduced weight. A small charger could be located in juxtaposition to the Motorette control box, e.g., just to the right of the actuator (see Fig. 5 and 6).

Many arbitrary "design" choices were made for the sake of expediency. The $3 \times 16 \times 16$ in. plastic-covered foam cushion was selected on the basis that many quadriplegics use these. The backrest is an upholstered piece of curved sheet metal, similar to the plastic ones in manual folding wheelchairs. Basic research on cushions is being carried out at other places (13). The only restrictions on the design of the seat part of the UC wheelchair are that it articulate (for reclining) and that it be easy to transfer in and out laterally. This suggests a relatively flat seat (perhaps the armrests can supply the desired lateral support of a "bucket" seat). An electro-hydraulic actuator could have been used instead of the ball-screw unit, but the ram would have to have been double-acting (three telescoping, two concentric pistons moving out from one cylinder, sections). Also the ball-screw is completely self-locking, while the hydraulic one might not be, due to leaks which might even spill oil.

It was necessary for clearance purposes to use a central single-post support (Fig. 7) for the footrest. This concept seems to work very well. A fixed footrest appears to be adequate, but two inwardly folding ones could be substituted.

A more universally adjustable headrest has been developed.

Regardless of the number of expedient decisions, compromises, and "quickie" add-ons in the UC wheelchair, it is basically a useful device. It is a small package, very maneuverable and adequate in power, speed, and hill-climbing ability; it adds greatly to the "vertical mobility" of a quadriplegic; it goes through narrow bathroom or toilet stall doors and allows van driving or riding with good clearance and visibility; it has completely unobstructed lateral transfer capability; it is totally stable and safe with seat low under all speeds, acceleration, and inclination situations; it reclines for rest and pressure sore prevention; and its seat and occupant can be restrained for a 20 g frontal impact.

Not only does the UC wheelchair offer completely unobstructed lateral transfer, but the transfer also can be made in a downhill direction. The quadriplegic occupant simply raises the wheelchair seat to a slightly higher level than the, say, bed and moves (or rolls) over and down into the bed. For transfer from bed to chair, he sets the wheelchair seat lower than the bed.

A "wheelchair" may not be the best short-range mobility vehicle for severely handicapped people. But, given present understanding and

state of the art, it seems to be a good one. Wheels, although they in no way replace the myriad of leg functions, are excellent low speed, low friction, devices for transport on relatively smooth, level, to say, 10 percent grades. Three wheels are needed for stability, but four is a better number, as long as the frame or suspension system allows ground seeking (four wheel contact) at all times on warped surfaces. D.c. battery power is the expedient now since fuel cells are not operatioinal or too expensive; internal combustion engines are prohibited for use indoors. Pneumatic power is efficient (if a very high pressure air tank is used) but energizing high pressure tanks periodically is beyond the present state of the art.

CONCLUSIONS

The following sizes, characteristics, features, or functions have been built into the UC wheelchair, or will be by the time of this publication:

1. A 17-in. increase in vertical mobility or reach compared to a fixed-seat wheelchair.

2. A 21.0-in. wide by 39.5-in. long by 60.0-in. high (head of a 5-ft.-8-in. person) package with seat at a 27-in. height; a 24.5-in. wide by 58.3-in. long by 42.3-in. high package with seat at a 10-in. height; and a 24.5-in. wide by 54.5-in. long by 49.5-in. high package with seat at a normal 18-in. height.

3. A total unoccupied weight of 256 lbs.

4. A speed of 7 m.p.h. on the level and 3 m.p.h. on a 6 percent grade, carrying a 180 lb. person.

5. A turning diameter, between vertical walls, of 40 in., with seat at 27 in.; a 59-in. turning diameter with seat at 10 in. and backrest up.

6. A completely reclining back, with seat low.

7. Retracting footrest for close frontal approach.

8. Unobstructed lateral transfer provision.

9. Mechanical "pivots" at anatomical joints.

10. Adjustable to fit 90 percent of the population.

11. Two lead-acid automobile batteries.

12. Standard Motorette, joy stick pulse-width-modulation speed control unit for smooth, continuous speed variation.

13. Two drive motors.

14. Four mechanism functions carried out by a single actuator (Saginaw ball-screw).

15. Van driving or riding with wheelchair occupancy capability for a 6-ft.-6-in. person. Auto driving or riding could be accomplished for a 6-ft. person; a taller person would require special batteries (for lower seat height).

16. Excellence in the area of daily activities.

17. Protection in a frontal 20 g collision.
18. Anatomical joint and muscle therapy for knees and hips via the retracting leg rest — reclineable backrest feature.
19. Swing-away, adjustable armrests.
20. Positive gear drive.

CRITIQUE

The following shortcomings of the UC wheelchair are apparent:
1. It is expensive. The low bid for three prototypes was $4,100 each. This figure would be lower for a production model.
2. It is heavy (256 lb.).
3. The gears are noisy.
4. The elevating, narrowing, and reclining functions are not independent. However, this expedient greatly reduces complexity, size, and weight.
5. The 8-in. castor tires are heavy and hard.
6. Batteries are too high, heavy, and unshippable by aircraft (once activated with acid).
7. There is exposed grease on the male actuator sleeve cover.
8. Castor wheel, passive push-pull "steering" is a minimumly controlled, slowly-correctable scheme.
9. There are no parking brakes.
All other shortcomings of which the authors are aware will be corrected by the time of this printing (before the three test prototypes are built by Motorette).

PROPOSED FUTURE WORK (1975)
(In Order of Expediency —
On a Funding Available Basis)

1. Reduce the noise level in the gears. The manufacturer may contribute here.
2. Add "parking" brakes—essential for transferring and hill safety.
3. Replace the lead-acid batteries with dry, rechargeable (say Gel-Cell types), smaller (or at least more flexible in terms of packaging), deep-charge batteries. This could increase the wheelchair cost slightly. Motorette and a battery manufacturer are developing a lead-acid battery with a coagulated gel (instead of liquid) acid. This is a nonspillable, partially-vented battery which can be taken on airplanes. At this time Motorette is only putting the gel in conventionally-shaped commercial batteries. Another fabricator, Gel Cell, makes individual 2-v. battery cells of various shapes which can be placed in other configurations and

orientations—giving great flexibility in shape of space and location on the wheelchair. These new gel batteries are more expensive than their predecessors and their ampere-hour capacity is lower by 40 percent, but they last longer. Space-saving considerations would make up for this loss in capacity, since more cells could be added in some nook or cranny around the wheelchair.

4. Add a speed and acceleration limiter which will be brought into play when the seat is high.

5. Eliminate the castoring system and replace it with a "programed," electrically controlled positive steering scheme.

6. Design a simple, unobtrusive van lift for the UC wheelchair.

7. Finish the auto lift for the UC wheelchair with some possible compromises:

      a. enter the left front door, or

      b. enter the right front door, but drive from the right front side using special hand controls or an "English" right hand driving setup.

8. Design a new variable-seat-height manual wheelchair for paraplegics, without batteries, motors, and actuator (but negator springs for counter-balancing). Greater compactness, height variation, and versatility would be possible.

9. Design another new powered wheelchair which will climb a 12-in. curb or into a van with a single half-floor-height step (32 in. × 32 in.), and fit into a standard U.S. two-door sedan.

10. Design a pulse-width-modulation control box without mechanical relays.

11. Add a two-speed gear changer for higher speed on the level and more efficient hill climbing.

PHILOSOPHY

Simply put, there are two basic approaches to improving the physical lot of severely handicapped people. The approach which has been used mostly to date is to adjust the physical world to fit the physically handicapped person in, say, a wheelchair. An example is the current endeavor of many concerned groups to eliminate architectural barriers, such as curbs, hard-to-open doors, steps, narrow bathroom or toilet doorways, and high wall telephones, switches, etc. To the last might be added the need to adopt special tables, desks, workbenches, wall cabinets, and bookshelves to the reach or clearance associated with conventional wheelchairs. Barriers might be eliminated just in a home and office or in a whole community or campus. The latter approach is very expensive, particularly if there are few wheelchair users in the community.

The other approach (attempted here) is to try to adapt the wheelchair itself to negotiate or accommodate as many "barriers" as possible. If the wheelchair seat can be elevated, or depressed to any reasonable height, the user can sit under almost any conventional table, desk, bench, etc. In some cases a 2-in. or less thick table top will fit under the armrest and over the legs (see Fig. 1). Vertical walls can easily be reached in front with the seat high (Fig. 1). Reclining the backrest enables passage under a 24-in. high horizontal barrier. The drive system operates for all configurations. Retracting footrests plus the narrowing capability (Fig. 5 and 6) provide for very good maneuverability in small spaces; a 22-in. toilet stall door can be negotiated or a van interior (Fig. 8 and 9). A curb-climbing mechanism can be added (in a forthcoming model) which will allow a 12-in. curb traverse or climb into a vehicle with a 12-in.-high floor or, in two stages, one with a 24-in-high floor.

Of course old architectural barriers, and potential ones in new structures, should be eliminated as often as possible. After all, anything which makes mobility easier for wheelchair-bound people makes life easier for other physically handicapped, diseased, or elderly people. But, again, this is only one important approach. Designing "wheelchairs" to overcome many types of barriers is another worthwhile approach.

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MOBILE BED/WHEELCHAIR DEVELOPMENT[a]

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INTRODUCTION

The objective of this project is to develop a bed that has the physical dimensions, including width and features of a standard hospital bed, and that also has the additional feature of being capable of automatically folding itself into a configuration resembling a powered wheelchair, preferably no wider than a conventional wheelchair so as to enable maneuverability. Such a device would provide mobility within the confines of the hospital and its immediate area of level ground to a severely paralyzed patient without the necessity of transfer from bed to a conventional powered wheelchair. The most significant gain in rehabilitation which should accrue from the bed/wheelchair combination is the independent mobility available to such a patient without the necessity of waiting for one or more attendants and the nuisance of being transferred from bed to wheelchair by others. A secondary but important gain would be the very substantial savings in labor to the hospital's staff. If practical, such a bed/wheelchair device might also be very helpful to a homebound patient in a house designed with freedom from high door sills and steps, permitting mobility within the house and perhaps to an outdoor porch or patio.

The original predicted time for completion of this project was one year. Significant progress was made, however, after only 2½ months. The original production plan included two phases. Phase I was to fabricate quickly a first prototype that did not necessarily meet all of the specifications required of the final version but that was: 1. Capable of being folded into a semblance of a sitting position comparable to the ususal hospital bed; 2. electrically powered and equipped with a joystick

control system that could be operated by a paralyzed patient; and 3. possessing sufficient maneuverability to negotiate easily the halls and walkways within the wards and adjacent areas of a large rehabilitation hospital (Rancho Los Amigos). It was believed that this first model could be fabricated with minimal expenditure of time and money to provide facilities for preliminary clinical evaluation. This hasty patient trial should indicate to a certain degree: 1. patient-user acceptance, 2. neighbor patients' attitudes, 3. attitudes of nurses and ward staff, 4. utility for patient transport, and 5. possible desirability of additional design features not originally conceived.

PHASE I

Phase I has been completed except for the accumulation of data from the preliminary clinical evaluation. Design of the vehicle was accomplished by shortening the under-carriage or frame of a standard manually operated foldable hospital bed (by cutting approximately 4 ft. from the head end) (Fig. 1 and 2). Under the shortened head end of this reduced bed was placed a 12-volt d.c. power drive system similar to the drive mechanism of the Scat electric wheelchair. This vehicle is controlled by a joystick proportional-control system operated by feeble motions of one hand.

FIGURE 1.—Phase I modified conventional hospital bed, with frame shortened approximately 4 ft. from head end. Head end rests on electric wheelchair drive unit with joystick proportional control system.

FIGURE 2.—Phase I modified conventional hospital bed.

Initial observations indicate that the device is exceptionally maneuverable in spite of its larger width and length compared with conventional wheelchairs and in many driving situations is actually easier to manage than a regular electric wheelchair. Only one patient, at the time of the conference, had used the bed/wheelchair, and his experience was limited to 5 days. Though no conclusions could be made at that time, a motion picture was shown illustrating mobility of the bed under control of the quadriplegic patient on walkways in the patios of the hospital and even across grass.

PHASE II

Phase II includes the design and fabrication of an improved device with the following features:

a. In the bed mode, the device was to have all of the physical dimensions and characteristics of a standard electrically powered hospital bed.

b. In a wheelchair mode, the device was to have a structural configuration similar to a normal electric wheelchair, though slightly larger than the average wheelchair.

c. Conversion from mode one into mode two was to be automatic, requiring the patient to make only one input control command.

d. Driving control in the wheelchair mode was to be proportional and adaptable to any type of control transducer, i.e., joystick operated by hand or by chin cup, puff or sip, tongue control, etc.

Phase II likewise involved modification of an essentially conventional

hospital bed, starting with shortening of the frame and mounting the shortened head end of the bed upon a modified Scat wheelchair drive mechanism (Fig. 3). In addition to the motorized drive for the entire structure, motorized drives of the bed folding mechanism are also provided, as in many conventional hospital beds in present day use, in contrast to the hand cranks for elevation of knees and of back as provided in the Phase I model. Legs with small casters are provided under the head end of the bed for additional safety, but normally they clear the floor with weight carried only on the casters at the foot and on the driving wheels of the modified wheelchair motor mechanism. Additional battery capacity is provided to operate the bed folding as well as the mobility feature. A foam rubber mattress is used in contrast to the conventional tufted mattress.
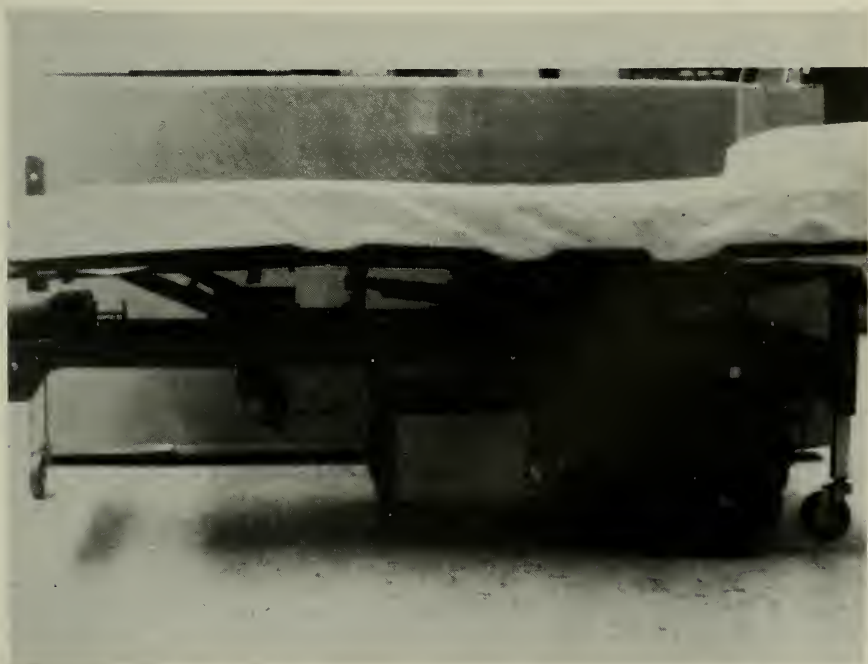
FIGURE 3.—Phase II modified conventional hospital bed on electric wheelchair drive. Knee and back elevation are also motorized.

As shown in Figure 4 (a view from the head end of the bed), the full width of the hospital bed is available when the structure is flat in the conventional bed mode. The control unit can be swung out of the way by an attendant to facilitate nursing care.

FIGURE 4.—Head view of Phase II bed showing full width in flat position. Control box can be swung to the side when not needed.

A foldable steel frame is provided to allow: 1. narrowing of the bed and 2. buckling of the foam mattress into a trough-like configuration, both to protect the patient and to make the wheelchair configuration narrower than the conventional hospital bed, as illustrated in Figures 5 and 6. Universal joints in the side rails supporting the outer edges of the mattress (Fig. 7), transmit to each section the torque derived from cranks at the head of the bed attached to cables anchored to the base of the bed, and thus tensed when the head of the bed is raised, as shown in Figure 6. The cells of the foam mattress apparently collapse sufficiently to prevent undue buckling of the mattress in the hip area, as might occur with more conventional mattress designs. In the chair configuration, with the side portions narrowed, these side portions appear to be equivalent to segmented bunk rails rather than to the horizontal supports under the mattress which they form in the flat bed configuration.

FIGURE 5.—Side rails fold upward and inward when legs and back are raised into the chair position, forming the foam rubber mattress into a trough-like configuration.

FIGURE 6.—Head of bed/wheelchair, Phase II, shown in raised position, tensing cables attached to cranks on side portions forcing them to rotate and thus forcing the mattress into a narrower trough-like configuration.
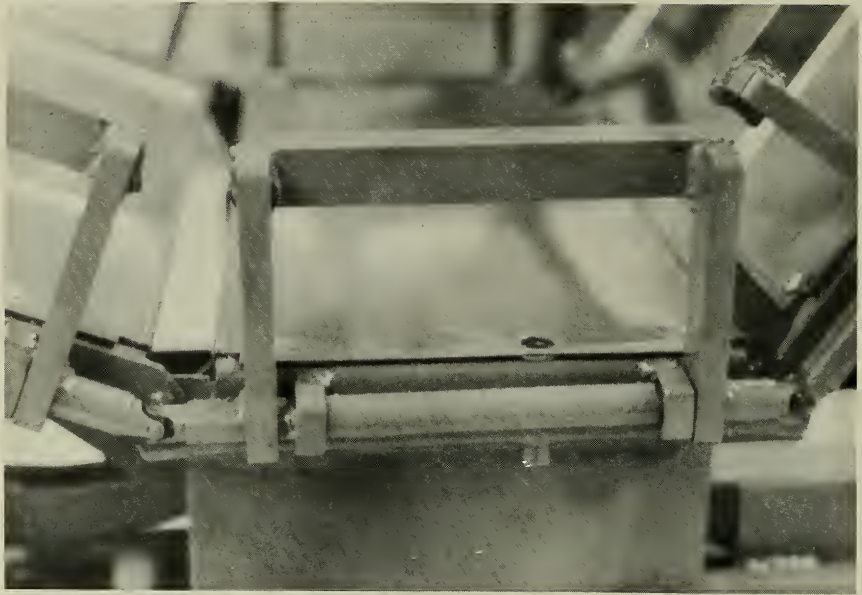
FIGURE 7.—Closeup of universal joints in side rails transmitting torque to rotate side portions.

In the Phase II configuration, a joystick control with a chin cup for control by a severely paralyzed patient is mounted on a box supported from a post at the head of the bed. It is anticipated, however, that several other types of control can be supplied to meet the needs of individual patients.

Additional motion picture footage, not available at the time of the Chicago conference, has been prepared to demonstrate mobility of the Phase II bed both indoors and outdoors.

PHASE III

Supplementation of the project has been requested to permit construction of a third bed as a prototype for a finished product, in contrast to modification of existing commercial hospital beds. While this is under design and construction, clinical trials of the first two models will continue.

DRIVER SAFETY IN MODIFIED VANS

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INTRODUCTION

The concept of a handicapped driver remaining in his wheelchair while at the controls is now a reality. The modification of "van-type" vehicles to permit easy access by an unaided handicapped person has achieved considerable popularity and is very useful to persons whose ability to transfer is marginal or who are unable to transfer unaided. The prospect of independent mobility for the handicapped has opened many opportunities for employment and recreation that did not exist before. The paraplegic has less of a problem than does the moderately severe quadriplegic. Simple hand controls are satisfactory driving aids for the paraplegic. Something more sophisticated is required for the quadriplegic with limited power and range of motions. Control systems have been developed which permit the moderately severe quadriplegic to safely operate a van-type vehicle.

The continuing problem is an adequate and safe wheelchair and driver's seat combination.

CONTROL SYSTEMS

Mobility Engineering has, during the last 8 years, developed a driving system addressed to the quadriplegic who has limited power and range of motion and with reasonable eye-to-hand coordination. This system consists of fully boosted steering and brakes and throttle controls brought to a single lever within easy reach of the patient. The control column is statically balanced to eliminate reaction to acceleration and braking forces. Hand grips of various types are adapted to the patient's particular requirements.

The steering is mechanical hydraulic using an engine-driven pump as a primary source and an electrically driven pump to provide steering control in the event of engine failure. The emergency system is automatic; however, there is a provision for manual control by the driver.

The brake system is vacuum-powered and consists of a dual tandem boost system. Each system has an independent vacuum source.

Forward motion of the control column actuates the throttle, lateral motion of the top of the wheel steers, while motion to the rear applies the brakes. The maximum force required in any direction is 6 oz. The lateral range of motion is a 9 in. diameter semi-circle. Fore and aft motion is 4 in. to 6 in. maximum.

Since the quadriplegic cannot manipulate the instrument panel controls, all electrical driving and environmental controls are brought to a series of touch controls within easy reach of the driver. Provisions are made for duplication of any of the controls on the column as required.

Figure 1 shows the general arrangement of the cockpit controls.

FIGURE 1

DRIVER SEATING

During the development of the control system it was assumed that the patient would remain in his conventional powered wheelchair. Nagging problems with the use of conventional chairs continually occurred:

1. A tall individual in a conventional chair with a typical 5-in. cushion ran out of head room. While the van-type vehicle offers about 50 in. floor to ceiling, it is clearly inadequate in many cases. The first thought is to lower the floor or to raise the roof. Both of these are major structural modifications and require great care, since all current van-type vehicles are integral body and frame construction and removal of sections can seriously weaken the structure.

2. The conventional powered chair is essentially a folding chair with beefed-up wheels to which have been added a battery motor and controls. Even the most cursory analysis indicates a serious structural strength deficit. Add to this the lack of head restraint and lateral trunk restraint and the problem becomes more complex.

Although somewhat ambiguous, the Department of Transportation requirements for the driver's seat to be able to withstand 20 g and the seat and driver combination to withstand 4 g are considered minimal requirements.

It becomes obvious that a complete new look at a set of special specifications for the wheelchair driver is required.

DRIVER'S SEAT REQUIREMENTS

The following is a list of minimum requirements which must be met by a suitable seat:

1. Must maintain the indoor maneuverability of the conventional chair.
2. Must be adjustable in height by the user at will.
3. Must have structural integrity allowing it to meet the minimum Department of Transportation restraint requirements.
4. Must have a headrest.
5. Must provide good hip and torso lateral restraint.
6. Must provide for good patient posture and maximum distribution of weight.
7. Must have improved performance outside the house both in speed and on rough terrain.

While these specifications appear formidable, a careful look shows that we have the technology and most of the hardware on the shelf. It only needs development.

Seat Design Progress

Vans with good control systems are on the road now. With this urgent

requirement, it was decided to approach the problem in two phases. The first phase would be a compromise based on utilizing existing commercially available components with the primary objective of safe driver restraint. The second phase was to be a new design to address the total requirements.

Phase I

Two chair systems utilizing the principle of height adjustment were under development. One system is by Professor Cunningham of the University of California at Berkeley. This development offered many advantages but was not yet commercially available. The other system was produced by Wheel Chairs, Inc., and developed by Mr. James Allen at Rancho Los Amigos. This unit was commercially available.

The elevating base unit of Mr. Allen's chair was utilized. A molded, reinforced Fiberglas contour seat was adapted to this base with a special high strength chrome molybdenum tubing interstructure between the molded seat and the base to permit the loads to be taken from the seat directly to the van floor structure (Fig. 2 and 3). A special hold-down structure with rear access and an electrically operated lock completed the system (Fig. 4).

Bilateral shoulder restraints and lap safety belt attached to the interstructure were provided.

Flip-up armrests and an articulated footrest completed the interim seat arrangement.

This seat has been installed in the VA units and several civilian vehicles.

Several problems still exist. However, the basic problems of head room and safe restraint are greatly improved.

Phase II

Phase I experience has brought to light a serious problem. While the contour seat appears to have many advantages, the posture of the patient and upholstering to achieve good weight distribution need careful attention. Therefore, the design problem is divided into the base unit and the seating.

The Base Unit

1. Center Section

In order to provide a rigid high strength structure to transmit the loads from the seat and patient to the van floor structure, a box center section was designed which provides for engagement and locking with a mating floor structure when in the lowered position.

FIGURE 2

2. Suspension

A totally rigid wheel attachment to the center structure would have been more easily accomplished but would not have allowed accommodation for uneven terrain.

Therefore, the wheels are attached to the center section by two leading and two trailing arms. The trailing arms incorporate the driving motors and drive train for the rear pneumatic tires and wheels.

The leading arms are a four-bar system to maintain the front wheel
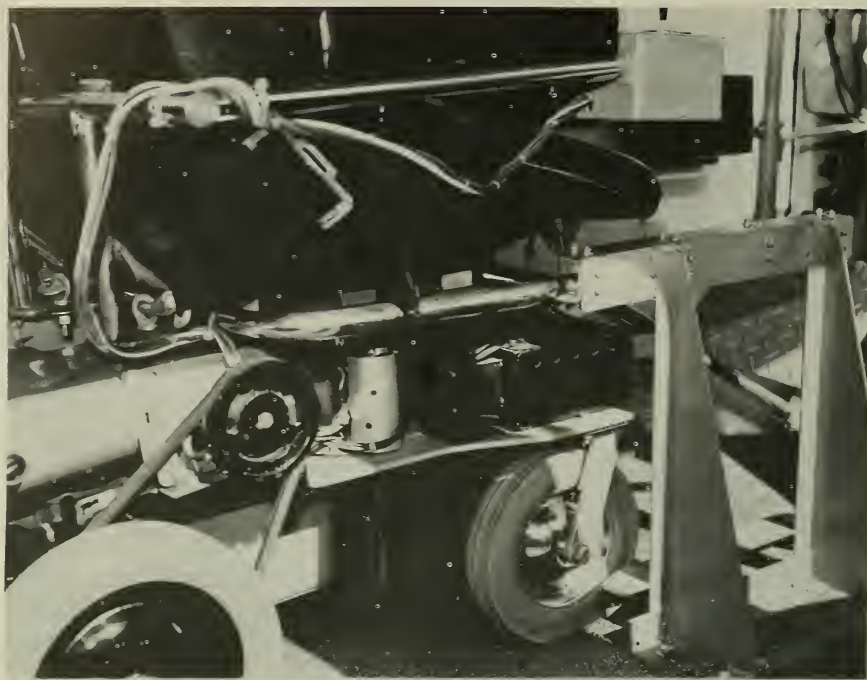
FIGURE 3

steering system in a vertical position. The front wheels can either be castered or power controlled.

Each of the four arms is attached to the center section by two transverse shafts—one for the two leading arms and one for the two trailing arms. Each arm connects to its shaft through a rubber torsion spring. An antisway torsion bar connects the two leading arms and may be added to the rear arms. In this way each of the suspension arms is independent of others. This should provide a relatively soft ride and excellent "rack" accommodations.

3. Height Adjustment

Two electromechanical actuators will provide rotation of the two transverse suspension shafts. In this way the angle of the suspension arms, relative to the base can be varied by the patient and as a result, the height relative to the ground can be varied. With the arms horizontal,

FIGURE 4

the seat will be in its lowest position (Fig. 5). Rotating the arms downward approximately 35 deg. will raise the seat 8.5 in. to its highest position (Fig. 6 and 7). Since the front and rear arms can be controlled independently, some limited degree of seat tilt can be obtained. Two torsion springs will be used to offset the static weight.
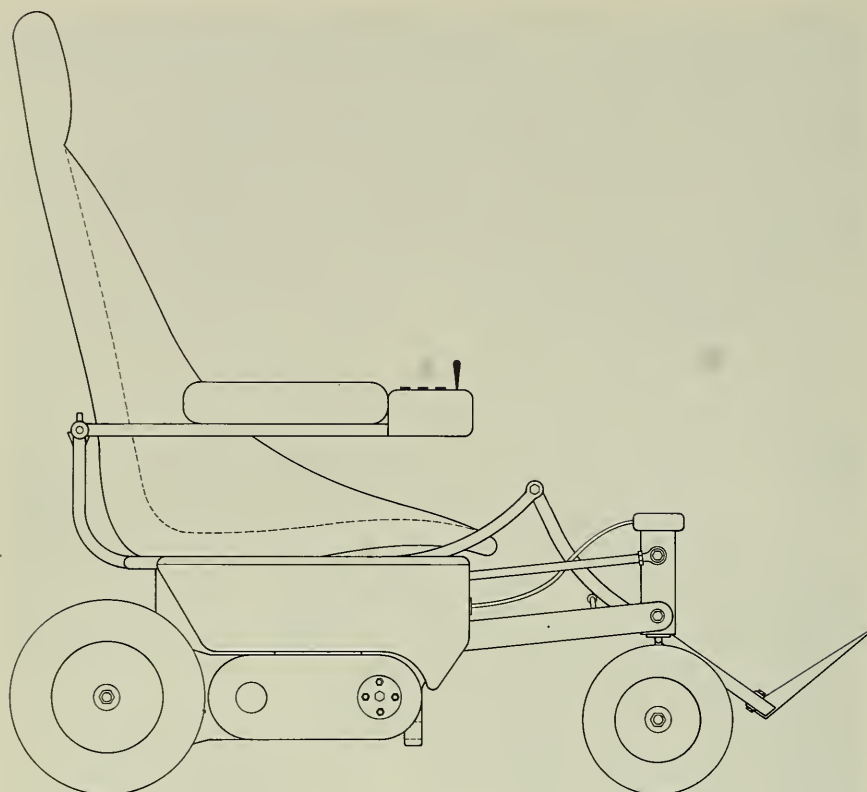
FIGURE 5

4. Steering System

The requirements for higher outdoor speeds and rough terrain operation make castered front wheels undesirable. The shimmy characteristic of higher speeds and poor directional stability of caster wheels on rough surfaces would require the use of a rather complicated damping system. The system we have chosen involves powered steering
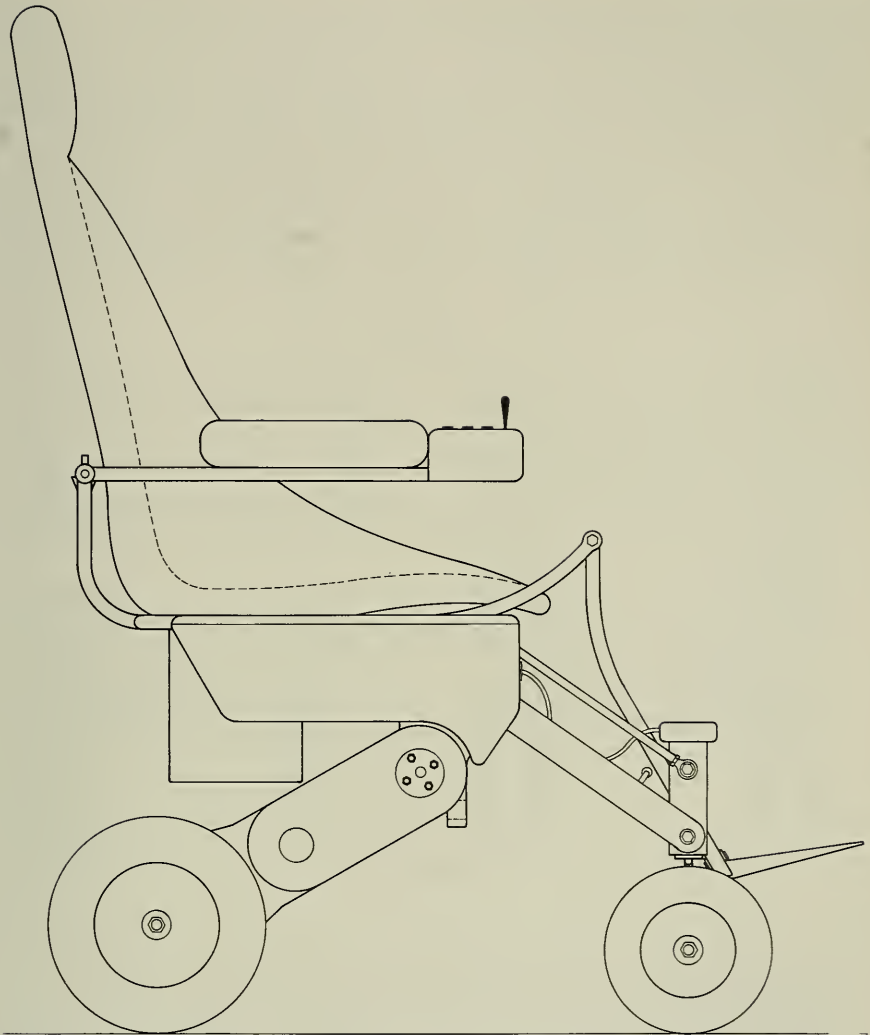
FIGURE 6

through a closed loop continuously variable servo mechanism. The front wheels will be steered through 200 deg. or 100 deg. right or left from neutral. Reversal of the power to the inside wheel will occur at approximately 60 deg. from neutral in each direction.

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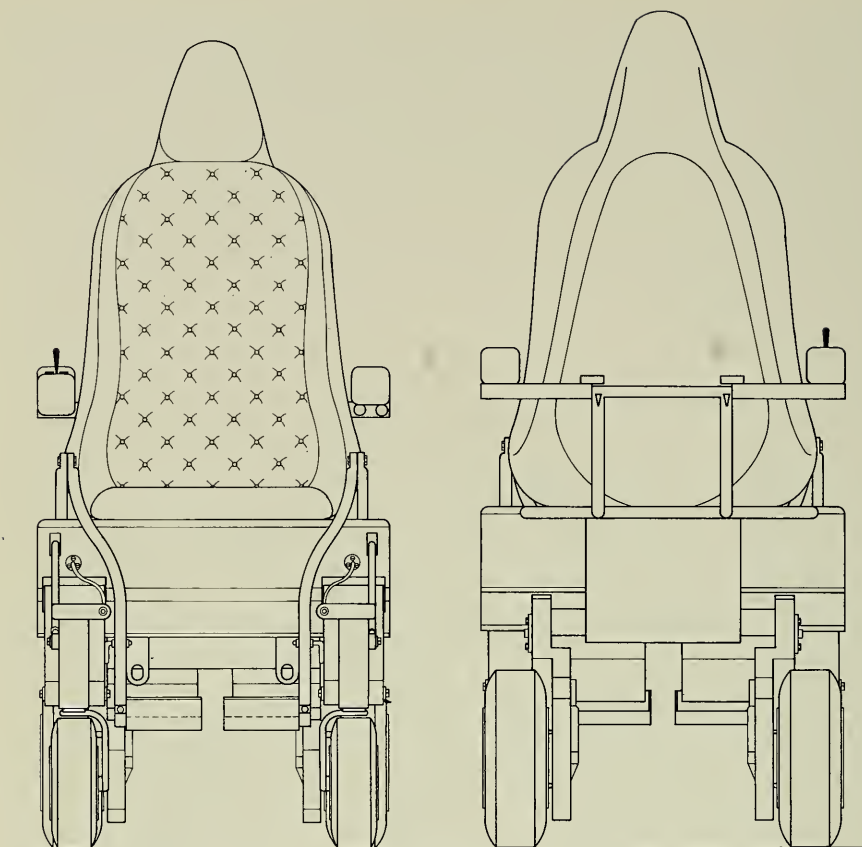
FIGURE 7

The steering servo system and the power control use a common ramp generator system and are contained in the same control unit.

Steering and power control will be through a single joy stick. The electronic control system has been designed specifically to the chair requirements and involves the use of the latest integrated circuit techniques with resulting miniaturization of the package and greatly improved efficiency.

Seating Design

The problem of obtaining an optimum seating arrangement which will meet the requirements of safety, trunk stability, and comfort is being approached in several ways.

It appears that a series of clinical trials with an adjustable seat is the best way to establish the best posture and the range of widths and seat

lengths necessary to accommodate the range of patient dimensions. An adjustable seat is now being prepared. Trials will be made with a series of quadriplegic patients representing a variety of sizes and disabilities. These data will be used to design a range of seat sizes, hopefully narrow, that will accommodate a wide range of patients.

The area of contour molded cushioning incorporated in the basic form is being explored. Prototype seats are planned.

These and other approaches planned will, we believe, result in acceptable compromise which will meet the ultimate requirements.

SUMMARY

Although many areas are open to continuing development, the fact is that we can *now* deliver a safe system by which a large portion of the world's quadriplegics can be given independent mobility. Although imperfect at present, it is hoped that continuing development will bring the systems nearer the ultimate goal.

SAFETY DURING MOBILITY

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Our efforts during the past year have been in three areas. The first activity has been development of foam cosmetic covers for prostheses and is described in the report on "Cosmetic Covers for Limb Prostheses." The second activity has been cooperation with the VA Prosthetics Center on evaluation of commercially available automotive hand controls and development of standards for these devices. Anton Reichenberger discussed this activity in his report on "Mobility Aids." The third area is development of an automobile driving system for use by a target population which we will characterize as a C 5-6 quadriplegic. This system is to be an economical, reliable, modular, component system that can be standardized in the future by the auto industry. The key concepts here are modularity—which allows use of selected components on a prescription basis at a reduced cost—and standardization by the auto industry.

We began research in this area by enumerating and then analyzing all of the aspects of this driving problem; the task begins with the individual in his wheelchair outside the vehicle and ends when he has reached his destination and has exited the vehicle. Analysis in this manner allowed us to recognize four broad problem areas which could be treated more or less independently. The first area is the entry-exit system, which in turn relates to the type of vehicle being used; the second area is seating and restraint systems; the third area is the driving task; and the fourth

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area is any additional safety features (foam filled gas tanks to contain fuel in case of rupture, communication systems, etc.).

Fortunately, some of the problem areas have already been addressed. Dr. Cunningham's electric wheelchair, with its special features of variable height, floor lock, and shoulder harness, appears to be well suited for people desiring to drive a vehicle without having to be bodily transferred to the driver's seat. The vehicle selected is a van with a side-entry sliding door. This type vehicle is currently being used by many individuals who drive from a wheelchair by using hand controls. Various entry-exit systems are commercially available which consist of electromechanically operated lifts and door opening and closing systems, and some of these are adequate for our purpose.

By using available (or soon to be available) components for entry-exit and seating, we were able to concern ourselves primarily with the driving task. This task we further divided into operation of primary control systems and secondary control systems. Primary controls are defined as acceleration, braking, and steering. Secondary controls are defined as all other controls necessary for driving the vehicle. The obvious unifying characteristic of this classification is that the primary systems are all vital to safe driving. However, from an engineering point of view the primary controls all require proportional controllers in contrast to the secondary controls which require only on-off switches, or at most multiposition switches. Once the driving task is broken down in this manner it becomes obvious that one should automate as many of the secondary controls as possible, so that the disabled driver can concentrate his capabilities on operating the primary controls. For example, we have developed a "rain sensor" which automatically controls the windshield wipers.

In June of 1973 we received a van and began to transform the concepts which we just discussed into actual hardware. A brief description of the van as it is currently configured follows. The primary controls are operated by a two-axis joystick which drives hydraulically powered steering, pneumatic braking, and mechanical acceleration. All normal controls are retained and either the normal or joystick system can be used.

Secondary systems are now available for control of ignition, lights, windows, wipers, and emergency brake. In addition to the above hardware required for driving, we have installed instrumentation to measure and record all of the primary control inputs (accelerator position, brake position, and steering position) and the resulting vehicle responses (distance, speed, and acceleration). This instrumentation will be used in an evaluation of the primary control system.

The joystick control system has been qualified to date by using this system to pass the Texas Department of Public Safety driver licensing test by a normal driver using the joystick controller. The vehicle is very

controllable at both city and highway speeds and a minimum amount of training is required. We have not yet had any disabled drivers; however, we are scheduled to have the necessary entry-exit equipment commercially installed this month to give us the minimum for driving by the target disabled driver population.

We plan to concentrate in the coming year on evaluation and improvement of the existing systems and addition of backup components to insure a fail-safe system. Evaluation will consist of first evaluating the vehicle performance and then attempting to determine the best man-machine interface for operation of the primary controls by a C 5-6 quadriplegic. Experiments were conducted during the past year with 50 disabled subjects to compare various joysticks for a tracking task. For the driving task we will compare a small joystick, similar to that on an electric wheelchair and installed in a crash-pad-type dashboard, to a cradle or splint-type device which will be attached to the arm to allow control by more gross movements of the shoulder and arm. A second objective for the coming year is to interact with the major auto manufacturers in an attempt to elicit their cooperation in making this equipment available in standard vehicles for both quadriplegics and normal drivers, since we feel that many of the automated units offer increased safety to the general population as well as to the disabled.

PARAPODIUM FOR ADULT PARAPLEGICS

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BACKGROUND

The Problem

The brace and ambulation system discussed in this paper is designed primarily for adult paraplegics. Paraplegics, as a group, spend too little time on their legs. We unequivocally accept the view of medical authorities, psychologists, and of the recently paralyzed themselves that it is of great importance for them to regain the capability of upright standing for at least part of the day.

The increased danger of decubitus ulcer development in sitting and a presumed need for weight-bearing in arresting calcium depletion from the bones seem to be an accepted belief by most in the medical professions. Many wheelchair-bound paraplegics also appear quite sensitive about their psychologically unpleasant need "to look up" to practically everyone else all the time.

To deal with others again "on their level" becomes a powerful incentive for great exertion toward mastering ambulation on crutches. An appreciable number of the younger and stronger paraplegics have been successful in learning to ambulate while wearing conventional long leg braces. However, it is also safe to say that not all paraplegics can build up enough persistence and upper body muscular strength to learn successfully how to ambulate on crutches. This is very difficult. Others who try do not achieve this goal until years have passed after their spinal cord injury.

Somewhat tragically, all the investments by many people in various ways too often end up to be an exercise in futility. Of the paraplegics discharged from most rehabilitation centers on crutches, all but a few return in wheelchairs, as was already observed in 1956 by Dr. Henry L. Heyl, a neurosurgeon and a paraplegic himself (1). Those who succeed in learning ambulation become eventually tired of doing things the hard way. All those paraplegics we have known have eventually returned to the ease of the fulltime use of a wheelchair for the simple reason that they gained nothing from ambulation on crutches that they had not attained already with a wheelchair.

It is for these reasons that we focus on new methods that:
1. Are quickly and easily learned.
2. Are easy to use without undue exertion.
3. Leave the hands free and available to do something worthwhile while standing.
4. Tend to develop greater access to a large portion of the world presently off limits to independently moving paraplegics.

Related Work of Others

True crutchless standing first became a reality through the 197ʊ development of the "Parapodium" for children by Wallace M. Motloch at the Ontario Crippled Children's Center (2,3,4,5). The Parapodium is essentially a lightweight standing frame that is not tied to the floor, but is worn by the paraplegic. We were very impressed with this approach to full body bracing because of the apparent ease with which paraplegic children could don the brace, stand in it without crutches, and ambulate with crutches.

The pivot walk method of forward locomotion was also first developed for children by Motloch at the Ontario Crippled Children's Centre (6). Motloch had previously developed a practical swivel walk prosthesis for legless thalidomide children (7,8) along the lines suggested by Spielrein (9), and similar to further developments by Barry, Duncan, and Klein in Australia (10,11).

Rose and Henshaw in England have reported success in extending the original swivel walk prosthesis principle to the bracing of both children and adults having complete but paralyzed lower limbs (12,13,14,15). Motloch felt, however, that the greater stability of the pivot walk improvement is needed for safe bracing of children with legs, a view which we share for our work with tall adults.

Both swivel walking and the pivot walk improvement produce a step forward by a partial body rotation around a vertical or near-vertical axis. The center of clockwise rotation for one step is behind and slightly outside the right shoe heel in pivot walking. Counterclockwise rotation for the next step is around a point behind the left shoe heel, and so on alternately for subsequent steps as is indicated in Figure 1. In swivel walking the respective points of rotation are where the soleplates touch the floor. One "foot" actually leaves the floor, at which time the base of support area on the floor becomes much smaller than it is in pivot walking.
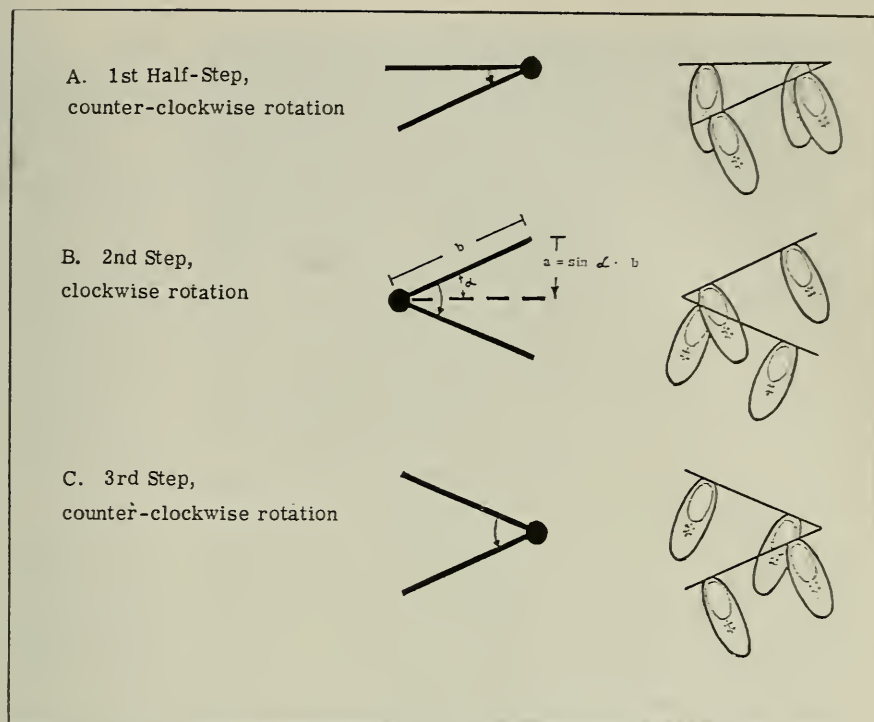
FIGURE 1.—Pivot walking, an improvement on swivel walk ambulation in that both feet stay in contact with the floor at all times, and the base of support area on the floor is therefore larger during forward steps. The diagram illustrates how a forward step is caused by body rotation around a point near the center of one heel.

Still other mechanisms of this class of forward locomotion are being developed by Glancy at the Indiana University Medical Center (16). In common with pivot walking, both feet stay in contact with the floor at all times, but there is dependence on crutches during forward ambulation.

We believe that endeavors to develop a practical crutchless robot system at the Mihailo Pupin Institute in Belgrade, Yugoslavia (17), will not be compatible with our desired timetable of reference, as we are committed to a realistic attempt of improving the situation of paraplegic Vietnam-war veterans before the last has resigned himself to a fulltime life in the wheelchair.

Feasibility Experiments by Prast Research Associates, Inc. (PRA)

An experimental adult version of a Parapodium was manufactured in 1971 to establish empirically whether it would be feasibile to extend the crutchless standing capability to a 6-ft. 2-in. tall paraplegic. Naturally, substantial design changes were necessary as we had to cope with new ratios of height- and weight-to-rigidity characteristics. Greater structural rigidity (anterior-posterior, lateral, and rotational) was in part achieved by a more suitable structure geometry. Early feasibility testing took place in 1972 with the cooperation of the VA Hospital, Castle Point, N.Y., and the Orthotics Laboratory satellite facility of the VA Prosthetics Center located at Castle Point (18,19). Lengthy troubleshooting and debugging of the first experimental brace was necessary to improve strength reliability of locking mechanisms and to minimize pressure points. Crutchless standing had been achieved immediately during a first attempt in 1971 (see Fig. 2).

An adult pivot walk attachment was fabricated and installed during April 1972. Four days later, when our paraplegic used this pivot walker for the second time, his speed of forward motion was timed. He had covered 80 ft. in 210 seconds, a notable feat for any total paraplegic when in the upright position.

More important, it had been demonstrated that both the crutchless standing and this alternative form of ambulation required no training to speak of.

PROTOTYPE BRACE DEVELOPMENT

Having decided that enough information was gathered to justify this, the design and fabrication of a new prototype brace took place later in 1972 and 1973. The new design reflects in many ways what was learned during the prior experiments (see Fig. 3).

In March 1974, the Veterans Administration awarded a contract which provides partial funding for the present phase of this research (20). The objectives are to allow paraplegics to: don and remove the devices, rise to a secure standing position, move without crutches on level surfaces, negotiate small obstacles like doorsills (using canes or hand contacts with the door frames), pass through narrow doors, and return to sitting position.

FIGURE 2.—First experimental crutchless standing brace for adults. This is the first experimental configuration in which the author, a 6-ft. 2-in. tall paraplegic with a T-8 level spinal cord injury, stood for the first time on Dec. 5, 1971, without crutches. The pivot walk attachment is not yet installed.

FIGURE 3.—New lightweight crutchless standing brace with integral pivot walker.

Ease-of-Donning Improvements

The following marked improvements have now been achieved: It was possible to reduce the overall weight of the brace with integral pivot walk mechanism from more than 20 lb. to less than 10 lb. This was accomplished with the more extensive use of lightweight aluminum alloys, properly heat-treated for maximum strength, and with vacuum forming of plastic parts (see Fig. 4, 5, and 6).
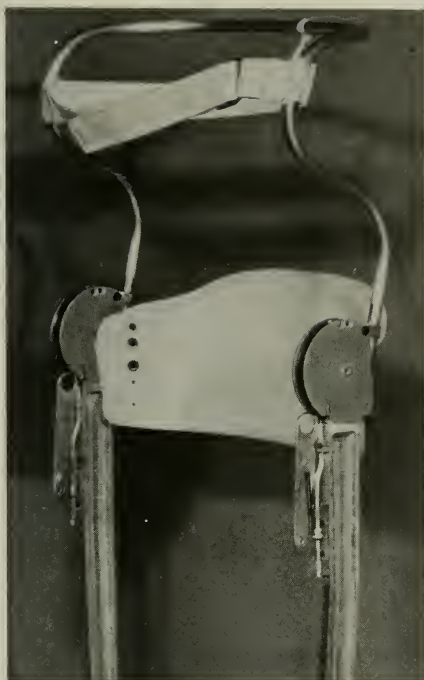
FIGURE 4.—Topmost portion of brace with vacuum-formed plastic backplate and hip joint hinges designed for automatic locking when adjacent brace sections straighten out relative to each other.

FIGURE 5.—Plastic knee supports and knee cage structure. Note the protruding tube section used for joining top-part module to this bottom-part module.

FIGURE 6.—Base portion of brace with plastic shoe supports and pivot walker mechanism. For counterclockwise rotation the paraplegic shifts his weight to the left, whereupon rotation around the white pivot point near the left heel can be initiated easily. The left pivot wheel, which then carries considerable weight, facilitates motion of this point at the perimeter.
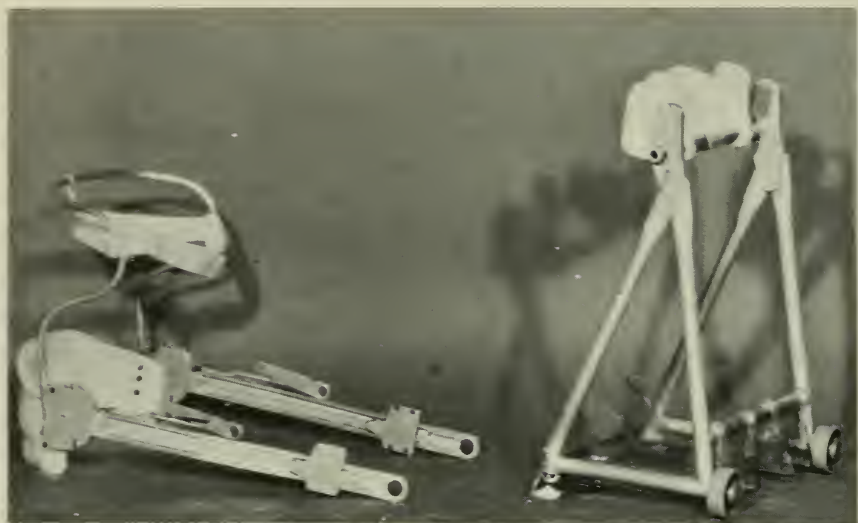
. FIGURE 7.—Top-half module and bottom-half module shown separated and in the positions used for donning by a seated paraplegic.

Moreover, the new lightweight brace is designed in two detachable parts. One of these modules is the top-half which provides hip joint support (Fig. 7). In donning, the paraplegic user slides this module behind the trunk, bringing it to its proper position while he is sitting. The bottom-half module includes the knee joint supports and the pivot walk mechanism (Fig. 7). The paraplegic places this bottom-half over his shins and knees, and manually inserts one foot at a time into the shoe supports. After both feet are properly in place, the top-half and bottom-half modules are ready to be snapped together (Fig. 8). It is now much easier to put each of the two modules in place—and then join them together—as compared to donning the entire first experimental brace at once. This is due to the greatly reduced weight and bulk which needs to be handled at one time. It has also been shown that it is less time consuming for an adult paraplegic to don and remove this new lightweight crutchless standing brace as compared to conventional long leg braces. In our opinion it is also easier.

TOP-HALF
MODULE

The Top-half and Bottom-half
Modules are detachable from
each other at the knee level

BOTTOM-HALF
MODULE

Vacuum-formed Plastic
Backplate for Hip-joint
Support

Hip-joint Hinges with
Automatic Locking

Plastic Knee Supports
are attached to tubular
aluminum support cage

Knee-joint Hinges

Plastic Shoe Supports

Pivot Points

Pivot Wheels
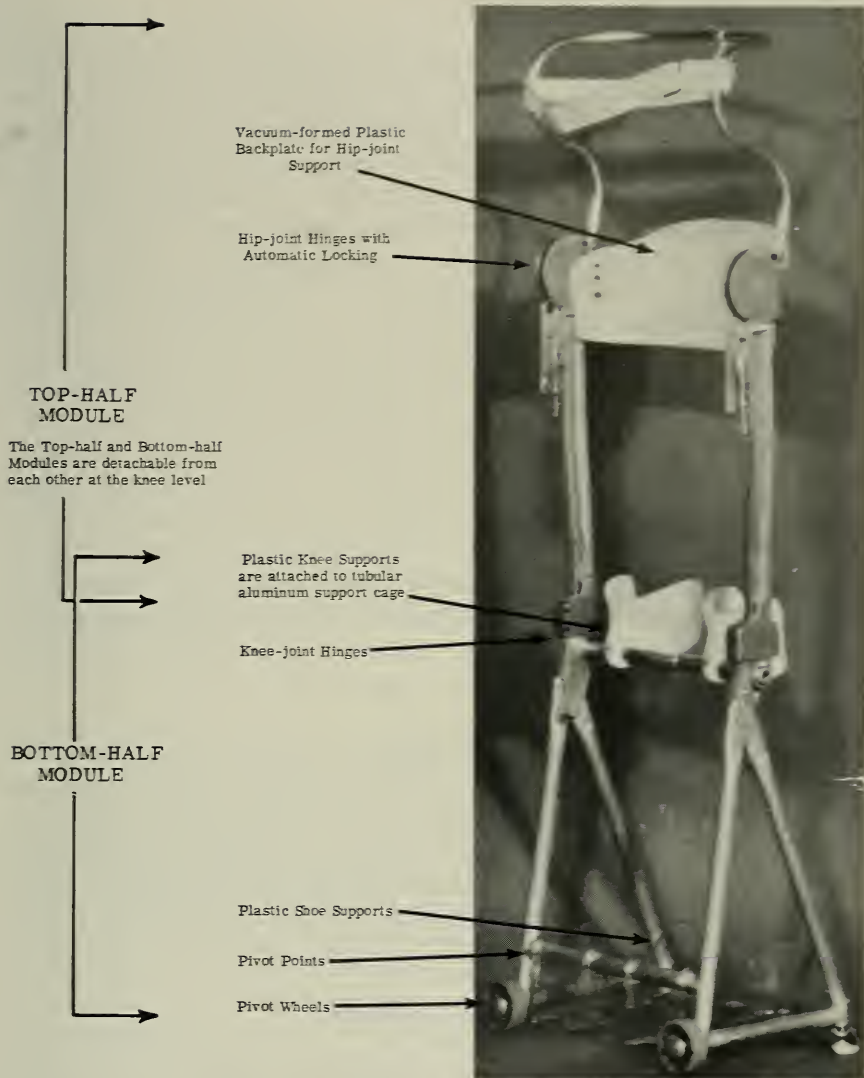
FIGURE 8.—Top-half and bottom-half modules joined together and shown in standing position. The two modules of this new lightweight brace are snapped together after donning them separately.

Toward Self-erection to Standing

The earlier experimental brace was already hinged at the hip joint and knee joint levels to make possible sitting as well as standing. The locks for the hip joint hinges now function automatically when the adjacent brace sections straighten out relative to each other. At present, the knee locks are manually locked prior to erection from a seated position, as is done with conventional long leg braces. In doing so, the hands are left free for use in pushing oneself upright into the standing position. This work is still in progress. Suitable test arrangements have been built to evaluate the most useful position for a paraplegic's hands in pushing himself up to the standing position. This is expecting to lead to wheelchair modifications in which the armrests could be flipped upward and forward. They would then serve as rudimentary parallel bars to aid in erection.

We learned in our early experiments of one disadvantage that adult paraplegics have relative to children. This is what makes the extra measures to aid in self-erection necessary. A child learns quickly that in the normal adult-scale world almost everything can be used as a grab bar. The adult paraplegic finds this not to be the case. Instead of pulling himself up to standing, he must be given means of pushing himself upward.

Next Step Plans

The obvious next step will have to be the continuing evaluation of this improved lightweight brace to determine whether weight reduction could have weakened the equipment too much for heavy day-to-day use.

Having determined that there is structural integrity through prolonged day-to-day use, brace fitting for additional paraplegics would require introduction of a multi-module design to accommodate individual size variations more easily.

BETTER ACCESSIBILITY

Few people seem to realize that much of the world is not open to paraplegics in wheelchairs. Many areas formerly inaccessible now become reachable with the crutchless standing brace. This is proving true especially in the case of access to rooms with excessively narrow doorways. A good example is the not-so-uncommon narrow bathroom door.

Pivot walking provides relief and allows the paraplegic to maneuver within a confined space. The required path width in pivot walking is a function of the length of the stride taken. The maximum width of the present brace is 18 in., allowing the paraplegic to clear doorways 22 in. wide by using short strides. We will demonstrate under the VA contractual requirements that doorways narrower than the standard 26 in. wide

wheelchair can be passed through. It will also be evaluated whether door sills will pose a problem.

Even the ability to just stand comfortably and safely with one's hands free makes a great difference in overcoming many other day-to-day problems. Many wall phones, book and display cases, cloth racks, kitchen cupboards, top drawers in filing cabinets, hat racks, outlets in vending machines, and bank teller windows are too high for the wheelchair-bound. Standing with crutches does not solve anything as long as one's hands are tied up. Standing without crutches makes all the difference in the world.

The techniques discussed in this paper are not meant to replace—but to supplement—the use of the wheelchair in areas where serious gaps exist in the paraplegic's total mobility system.

One of the greatest gaps, created by society, is the problem of stairs. Stairs are an important, if not the most important remaining unconquered barrier in the way to better rehabilitation of the paralyzed. A paraplegic could usefully function at many more locations if he could at least bridge the three-to-six-step stair barrier that now blocks his access to many public, business, and private buildings. We believe that the crutchless standing brace technology will become the first essential building block toward a future stair-climbing system for conquering that barrier.

SUMMARY

Paraplegics spend too little time on their legs because little apparent gain is received from too much energy expenditure. New methods, more responsive to user acceptance requirements, would have to: 1. be quickly and easily learned, 2. be easy to use without undue exertion, 3. leave the hands free to do something useful while standing, 4. open to independently moving paraplegics more of the presently off-limits environment of the world. Feasibility experiments are needed with an experimental adult version of the Parapodium established in 1971/72 to prove that crutchless standing and pivot walking are possible for tall adults.

The prior work led to the design and fabrication of a new lightweight crutchless standing brace. Marked improvement in regard to weight reduction was achieved. The new brace is designed with separate top-half and bottom-half modules, which are joined together after donning. This feature, along with significant weight reduction, made donning and removal much easier than in our first experimental model.

Test arrangements have been built to evaluate the most useful positioning of hands in pushing oneself from sitting to an upright standing position. This is necessary due to a disadvantage adults have relative to

children. Children always find something in the adult-scale world that can serve them as a grab bar whereas there is a lack of things that could equally serve adults. Instead of *pulling* themselves up, adults must *push* themselves upright.

Pivot walking allows the paraplegic to maneuver within a confined space, such as through a narrow doorway. More important, one's hands can be freed to do something useful while standing, such as dialing a wall phone, or simply reaching things above the upper reaches of the wheelchair-bound.

It is thought that these new techniques will eventually help more adult paraplegics to graduate from the wheelchair. Perhaps more important, it will entice most to stay on their legs at least part of each day because of the greater ease in using these new methods, and because of an apparent feeling of safety. A significant lessening of the consequences of their lower-limb paralysis is therefore in sight for paraplegics.

Note: At the Conference of Prosthetics and Sensory Aids Research Leaders held in Chicago in July 1974 a 6-minute film was shown as part of the author's presentation. Highlights of this film include:
1. Pivot walking with crutches used as a redundant means of maintaining balance, but not weight-bearing.
2. Pivot walking without crutches.
3. Pivot walking including a point where the paraplegic stumbles. This episode is shown to demonstrate the ease of recovery.
4. Donning of the new lightweight brace.
5. Donning of conventional long leg braces showing the obvious time difference compared with the lightweight crutchless brace.

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IMMEDIATE POSTOPERATIVE APPLICATION OF UPPER-LIMB ORTHOSES

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At the Richmond Veterans Administration Hospital in Virginia, considerable efforts have been directed by our upper-limb treatment group toward rehabilitation of spinal-cord-injured patients. Our group combines the skills of orthotists, physical therapists, occupational therapists, physiatrists, and hand surgeons as well as the salutory effect of students from each of these disciplines.

In 1971 we received funds for the purpose of developing orthoses which might be useful in speeding the treatment process and improving the results of treatment in our tetraplegic patients. Eventually the techniques learned and the need for a similar approach to patients with other diagnoses have led us to study other applications of the principle of immediate postoperative application of upper-limb orthoses.

Briefly, our rationale for immediate postoperative application of upper-limb orthoses is based upon the following assumptions:

1. A proper orthosis can be a more discriminatory method of immobilization than a postoperative cast.

2. An orthosis can be designed so as to allow motion at joints within a given plane of motion and within a given range of motion.

3. An orthosis can be adjusted more precisely and perhaps more easily than a postoperative cast.

Using a combination of available materials, other people's ideas, and our own ideas, we have been successful in demonstrating that our original assumptions were correct. Not only are they correct, but they can be usefully applied where the orthotist is skilled and the goals of design for the orthosis are understood by other members of the team who are treating the patient.

Since we began the development phase of our work, 24 entirely different developmental orthoses have been applied to 24 upper limbs. Each patient presented to the team a problem or a combination of problems requiring specific but differing design requirements from others we had treated. The tetraplegic or rheumatoid patient, as examples, display variable postural and mechanical problems which almost defy classification.

Our plan for care is as follows:

1. The patient is evaluated at a multidisciplinary clinic. If an orthosis is required for treatment, the prescription is written. If surgical reconstruction is decided upon and we feel that bracing will be useful, a prescription for an immediate application-type orthosis is considered. If the immediate fitting orthosis has application in this patient the next stage is entered.

2. Fabrication of the orthosis with the usual felt padding is accomplished, and the necessary fitting and adjustments are done. Then the felt is removed so that the orthosis can be applied over dressings after surgery and will not be too bulky.

3. The orthosis itself is taken to surgery where it may or may not be autoclaved. Sterilization is done where the orthosis is applied as an integral part of the dressing.

4. Dressing changes after surgery are facilitated in many cases where an orthosis is included. Also, the patient is allowed early motion within the design capabilities of the orthosis as dictated by the goals of surgery.

5. Finally, at the time when dressings are completely removed, the felt padding for the orthosis is applied and therapeutic exercises can continue without interruption.

We have not had enough patient experience to allow us to conclude that the total rehabilitation time requirement has been reduced.

There are some positive benefits that we have observed and are worthy of listing.

1. Patients have accepted this approach, and the enthusiasm and attention of the team has been useful in rehabilitation.

2. More precise control of joints has been accomplished. Where immobilization, support, or mobilization of specific joints has been the design goal, the results have been better than with casts.

3. Wound healing has not been interfered with.

4. Joint stiffness has been less of a problem where early controlled motion is made possible by the orthosis or where specific joint immobilization is accomplished and uninvolved joints can be given freedom to move or be exercised.

Some of the indications where we have applied the principle of immediate postoperative fitting of an orthosis include: tendon repair, tendon transfers, tendon tenodesis, joint fusion, arthroplasty, arthrodesis, synovectomy, capsulotomy, and burn reconstruction (BPR's 10-16, p. 246; 10-17, p. 244; 10-18, pp. 267-269; and 10-20, p. 239).

New Materials

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New materials are primarily plastics for cosmetic appearances. Not only visual but tactual aspects are now receiving considerably more attention. Twenty-five years ago, big improvements were made by the introduction of rigid plastic laminates for artificial limbs; these revolutionized the limbs formerly made of rawhide-covered wood, leather, metal, or fiber. Recently, there has been a resurgence of interest in modular skeletal structures of metal or composites with resilient flesh-like foam covering. Now there is renewed enthusiasm for development of a strong, tough, skin-like structure which either can be adhered to the skin in the case of ears, noses, and other custom-formed maxillofacial prostheses, or can be used to make cosmetic covers for skeletal-type artificial limbs, probably largely by mass production with minimal custom forming.

Dr. Schweiger, a dentist, heads a maxillofacial restorations clinic at VA Hospital, Wilmington, Delaware. He and Dr. Lontz, organic chemist and biophysicist, are principal investigators in a program funded through a contract with Temple University. The goals are to evaluate the physical characteristics of current materials for cosmetic restoration, to search for and evaluate new materials, and to test them in a large series of cases.

Some of the older participants in the program will remember that Dr. Fred Leonard, of the Army Prosthetics Research Laboratory, a friend of Dr. Lontz, had been involved in some of the early developments of similar material for use in the cosmetic glove worn over the APRL mechanical hand. There is a current prosthetic interest as well in terms of cosmetic covering for the endoskeletal or tubular type artificial limbs. Mr. Mauch began a group of three discussions on that topic.

Dr. Krouskop and the Texas A&M groups have worked on an interesting system for preparing a thin stocking over the remaining leg of an amputee, turning it inside out, and filling it with a foam.

Great ideas have a way of recurring. Professor Radcliffe first started in the prosthetics research program at Narmco, in 1946–1947. Even then,

one of their concepts was an endoskeletal prosthesis with a foam covering to conserve energy and impact so as to protect the skeletal structure. A thin elastic sponge rubber tape provided further resiliency, and a cosmetic "skin" was pulled over that. It seems that successive generations of these problems of cosmetic covering return to similar solutions. Professor Radcliffe now offers current views, based on his experience at the University of California.

CURRENT STATUS—PROSTHETIC MATERIALS FOR MAXILLOFACIAL RECONSTRUCTION

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INTRODUCTION

A combined clinical service and research program has been in operation for over 1 year. The principal goal is to develop, qualify, and propose standards for prosthetic materials in terms of specifications for tactile qualities and endurance. These qualities are developed from standard stress-strain profiles which approximate those of living, facial tissue, and are clinically evaluated by the molding of actual prostheses for patient trial.

MATERIALS AND TESTS

Following appraisal and assessment of the stress-strain profiles of polyvinylchlorides, polyurethanes, acrylics, and elastomers, all of which have been used in maxillofacial prostheses in the past, we chose as our reference or base biomaterial polysiloxanes or silicone rubber as most commonly known.

TEST METHOD

From the conventional Instron stress-strain profile and durometer coding, the modulus of elasticity for a given material is obtained. This provides a measure for and of the "tactile feel" of this material. The ultimate strength and percent ultimate elongation are also obtained from the Instron stress-strain profile. From the percent elongation for a given material it is determined how to modify the formulation of the chemical components in the silicone prosthesis to achieve the desired softness and anatomical conformation to optimally match a patient's articulate features of mastication, speech resonance, and facial gesture.

RESULTS

The work to date has involved RTV (room temperature vulcanized)

silicones, and HTV (high temperature vulcanized) silicones. The RTV silicones are easy to handle and may readily be used by ordinary technicians in prosthetic reconstruction. The HTV silicones, however, require special tooling, metal molds, blending rolls, and special curing ovens. The stress-strain profile data on RTV and HTV indicate several advantages of the latter.

The tactile feel of RTV and HTV has been extensively modified with low and intermediate molecular weight additives. The HTV compositions mixed with a special catalyst provide considerably higher elongations at low stress, more replicative of anatomical structure, and considerably higher stress at breakage as in tearing.

Research has been done to adapt the HTV chemistry to fit that achievable in the routine prosthodontic treatment service facilities, obviating the need for expensive investment in special tools, molds, curing ovens, etc. The heat cured HTV elastomers are now capable of being made in ordinary dental stone molds rather than expensive specially made metal molds. A full range of tensile, durometer, and tear strength data on the modified HTV elastomers is now being developed, with the expectation that patients' preference and enthusiasm for wearing prostheses of the new compounds will be enhanced.

CLINICAL SERVICE

To date we have provided prostheses for 40 patients as tabulated in Table 1.

TABLE 1

Reconstruction	RTV and combinations	New improved HTV (MDX-series)
Aural	12	—
Orbital	8	—
Ocular	17	—
Nasal	21	—
Complex	3	1
Implant	3	1
Total	64[a]	2

[a] Discrepancy in total patients is due to research duplicate prostheses.

COSMETIC COVERS FOR LOWER-LIMB PROSTHESES

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The idea for this cosmetic cover grew out of our efforts to develop a cosmetic cover for our tri-axial ankle mechanism. It became increasingly clear that existing cosmetic covers for ankle joints were not suitable for an ankle mechanism which provides rather liberal angular motion ranges around all three spatial axes.

After we arrived at a promising idea, we realized that its principle was also applicable to the problem of covering the knee joint of a pylon-type above-knee prosthesis, without interfering with its free mobility.

We disclosed this idea to Dr. E.F. Murphy, Research Center for Prosthetics, in a letter dated December 19, 1973, as follows:

> "The purpose of this new type cover would be to reduce to a minimum the friction and the torque bias imposed upon the knee joint by existing full length covers.
>
> The basic idea to achieve this goal could be characterized by two generic terms: modular design and simulation of nature. In practice this means that the soft tissue, mainly the calf muscle group and the anterior tibialis, would be made available as pre-molded foam elements and would be attached to the endoskeletal structure. The skin would be a relatively thin, easily stretchable stocking that would slide easily over the internal structure including the muscle groups mentioned, a patella-like element, and other bony protuberances. The muscle groups and bone protuberances as well as the 'skin' would come in different sizes which could be further varied by cutting off material in the appropriate places. It would be the job of the prosthetist to select the size that would best imitate the remaining good leg and assemble from these elements a cosmetically pleasing leg."

As a result of this letter, the VA authorized the filing of a patent. This has not been done yet, because we would like to wait until our work on the ankle version of this cover has progressed sufficiently to permit including into the patent application the results of some practical experience.

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COSMETIC COVERS FOR LOWER-LIMB PROSTHESES

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ABSTRACT

A soft cosmetic cover for use with modular endoskeletal prostheses is discussed. The reverse molding procedure, which is used to make a mirror image of a unilateral amputee's remaining anatomical limb, is described. This process reduces the time required to fabricate a cosmetic cover since no mechanical or artistic shaping is required to match the prosthetic limb to the anatomical limb. The resultant cover is composed of a lightweight (3 lb./cu. ft.) open-celled urethane foam which produces its own high-density, scuff resistant, and water resistant skin. This cosmetic cover greatly facilitates fabrication and increases efficiency in the production of modular endoskeletal prostheses for lower-limb amputees.

INTRODUCTION

Historically, the development of prosthetic limbs emphasized either cosmetic appearance or restoration of lost function. Advances aimed toward fulfilling either of these objectives were critically limited by the lack of surgical knowledge, which resulted in more than 75 percent fatalities of all surgery being performed. Very few survivors of amputation surgery had stumps which could be fitted with an artificial limb, since the amputation technique (using boiling oil and crushing the soft tissue to control bleeding) resulted in stumps with no weight-bearing ability.

However, many noteworthy advances have been made in the areas of surgery and amputee rehabilitation. These advances have spawned new teams of physicians, prosthetists, therapists, and recently engineers who

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have created a series of ever improving prosthetic appliances and amputee management techniques. These advances are summarized in References 1-5 and provide interesting insight into the evolutionary process which has resulted in a new generation of appliances. Simultaneously, these new appliances satisfy the need for a unit which replaces lost functions and provides a cosmetically acceptable appearance.

Accepting the CPRD design criteria which define the concept of total cosmesis, an endoskeletal modular prosthetic system has been developed for the lower limb. This new prosthetic system represents a merger of the materials technologies which resulted from the aerospace program with the knowledge paradigm associated with the prosthetics industry. By utilizing the endoskeletal weight-bearing-system concept in the prosthesis, a unit with improved function was achieved, but the innovations (6) did not produce a cosmetically acceptable system.

However, since the endoskeletal load-bearing system provides the load-bearing, jointed mechanism which is necessary for good function, the cosmetic requirments for the cosmetic cover were reduced to:

1. provide an easily cleaned surface,
2. provide a wear-resistant surface,
3. be able to be colored to match the skin tone of the amputee,
4. have no offensive odors,
5. have a natural texture, and
6. maintain flexibility at the joints after repeated flexures.

COSMETIC COVER DEVELOPMENT AND FABRICATION

The above criteria can be satisfied through the development of a cover which is fabricated from one of the new flexible polymeric foam systems. After evaluating several systems, a flexible urethane foam which generates its own thin, high density surface (approximately 60 Pcf.) was selected as the basic material for development. This open-celled foam system has an average density of 3–4 lb./cu. ft. and is manufactured commercially by Flexible Products Co. in Marietta, Georgia. The self-skinning characteristics provide a surface which is easily cleaned, abrasion resistant, and puncture resistant. Moreover, the foam system can be pigmented prior to the foaming process to produce a prosthetic appliance cover which matches the color of the patient's anatomical limb.

The urethane foam also meets the fourth design criterion once the gas which is generated in the foaming process is forced out of the foam. This is accomplished either by kneading the cover several times after the foam has cured or by placing the cured cover in a polyethylene bag and evacuating it.

The toughness and the thinness of the surface skin provide this foam with the characteristics which are necessary to satisfy the sixth design criterion. As long as the cover is not exposed to excessive heat, above 250

deg. F, or open flame, it has an expected life of more than 12 months; as a component in an experimental hip-disarticulation prosthesis, the foamed cover has undergone a 6-month clinical test without visible signs of failure due to flexure at the knee or hip joint.

In order to satisfy the fifth criterion and produce a cover which reproduces the anatomical characteristics of a unilateral amputee's leg, an inversion casting process has been developed which produces a well-shaped replica of the remaining limb without time-consuming sculpting. The steps involved in the process are presented in the following outline:

1. The patient's limb is coated with a thin layer of low viscosity (on the order of 50 centipoise) silicone oil.

2. One layer of cotton orthopedic stockinet is stretched over the limb.

3. The stockinet is coated with Liquid RTV silicone rubber.

4. Two layers of Banlon Orthopedic stockinet are pulled over the silicone-rubber-covered limb. This must be accomplished before the RTV vulcanizes.

5. A second layer of RTV is spread over the Banlon stockinet.

6. A nylon hose, preferably a panty hose, is pulled over the second layer of RTV, and the excess rubber is scraped off with the fingers so that the mesh of the hose is exposed at all points. It is this step which gives the foamed cover its texture so the texture of the hose is particulary important.

7. The mold is then permitted to vulcanize; this may require from 15–45 min. depending on the type of RTV employed and the amount and type of catalyst used.

8. The vulcanized rubber mold is then removed from the patient's limb by grasping the uppermost portion of the mold and pulling it over itself in the same manner that one removes a sock.

9. The tubular mold is then turned right side out again and the nylon stocking is removed. Care must be taken not to dislodge large pieces of the RTV. This will occur if the RTV has not been adequately wiped from the surface as described in step 6. If it does occur, the hose removal should be halted and fine sandpaper (180 grit) used to remove the excess RTV so that the nylon hose is exposed; then the hose may be removed with no damage to the mold.

The mold is then turned inside out so that the cotton stockinet is on the outside of the mold. This process produces a mirror image of the anatomical limb and is used to form the foam around the endoskeletal weight-bearing sytem.

To finish the construction of the cosmetic cover, the mold is suspended and the foam is measured, tinted, and mixed according to the manufacturer's instructions, and poured into the mold. Approximately 20 minutes after the pour, the one-piece cover which can undergo large

excursions as experienced at the knee may be stripped off of the mold in the same manner in which the mold was removed from the anatomical limb.

It should be noted that this sytem may be foamed directly around the pylon system, poured, and reamed out to fit over an endoskeletal system.

SUMMARY

The merger of aerospace materials technology with a knowledge of prosthetics has resulted in the development of a novel cosmetic cover which, when combined with an endoskeletal weight-bearing system, can provide an amputee with a cosmetically acceptable appliance which satisfies all of the cosmetic requirements set forth by CPRD.

COSMETIC COVERS FOR LOWER-LIMB PROSTHESES

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Cosmesis refers to four factors involved in the appearance and the feel of a lower-limb prosthesis in comparison with similar characteristics on the opposite limb. These factors include:

1. Shape: A general term including the matching of length, circumference, and cross section at various levels and the approximation of three-dimensional contours in such a way that the prosthesis appears similar to the opposite limb. In practice the actual circumferential dimensions must often be smaller in order to achieve the desired appearance.

2. Surface Feel: The degree of surface softness. A match with the characteristics of normal skin and soft tissue seems to be a desirable objective, if it can be achieved without a significant weight penalty. A close match with the feel of normal tissue is perhaps more important to the female amputee, but the sound-deadening characteristics of any soft cover is advantageous for all amputees.

3. Surface Texture: The appearance of the surface and its feel with a light touch should approximate that of normal skin.

4. Joint Continuity: The cosmetic cover should provide continuity of contour over the moving joints in such a way that gaps and bulges are minimized.

The ideal cosmetic cover for a lower-limb prosthesis has never been achieved because of conflicts between some of the above requirements. A lifelike soft feel is difficult to achieve without either loss of durability or excessive weight. A custom shape to match individual contours is possible at the expense of having to reestablish the skin-like characteristics after reshaping or by complicated custom-molding procedures.

An individual match of skin color leads to difficulties in providing good antistain and color stability properties. Easily applied color may not be sun and ozone resistant. A continuous cover over both ankle and knee joint requires special flexible materials which may lack durability.

A single solution to the problem is probably not possible because of differences between patients and the opinions and prejudices of both patient and prosthetist. Modern lower-limb prostheses should provide for a variety of types of cosmetic covers and cosmetic restoration systems

to allow for these differences. In all cases. however. the objective should be to approximate as closely as possible: 1. the shape of the opposite limb. 2. a soft and skinlike surface texture, 3. smooth continuous contours over joint surfaces. and 4. all of the above in an inexpensive, easily replaceable, durable, and lightweight system.

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Sensory Aids

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Twentieth-century developments in technology, particularly those related with World War II, in fields such as communications, sensing the environment at a distance, optics, electronics, and human factors engineering, have inspired inventors and scientists to work on sensory aids to help the visually and aurally impaired. The Veterans Administration was a supporter at the end of World War II of the National Research Council's Committee on Sensory-Devices (CSD) which guided government-funded sensory-aids research at a number of laboratories. A review of the field was published in 1950 in the book *Blindness*, edited by Paul Zahl, reprinted in 1962 (1). After the dissolution of this committee the Veterans Administration continued funding sensory-aids research projects aimed at developing, evaluating, or improving devices and services designed for easing the problems caused by blindness and hearing impairment.

The research projects reported on here are quite apart from the extensive medically oriented research conducted with VA in ophthalmology, otology, and other specialties having a clear relationship with visual and aural dysfunction. Here we are considering the device-oriented technologically based developments undertaken under the aegis of the former Research and Development Division, Prosthetic and Sensory Aids Service, and continued, after the reorganization of October 1, 1973, by the Research Center for Prosthetics under the Assistant Chief Medical Director for Research and Development.

Various devices and aids developed for the blind provide assistance in all sorts of pursuits a blind person may choose to follow. Many of these have existed for years, and a current display of what is available today may be seen in catalogs issued by the American Foundation for the Blind (2,3). Not available in the late 1940's were devices to enable a blind person independently to read an ordinary inkprint or typewritten page, and environment sensing device (suggested by the then dramatically reported sonar and radar systems) to afford mobility guidance to a blind person. Therefore, the VA concentrated its research efforts in these two

deficient areas, based partially on evaluation of CSD devices, further development reflecting new technology and insights, and further evaluation.

For more than 20 years the VA has funded a series of projects whose detailed histories may be traced by consulting the materials in VA's Bulletin of Prosthetics Research (4) and the Blindness Annuals (5) published by the American Association of Workers for the Blind (AAWB). These research projects have led to the availability at the present time of the "Stereotoner," an audible-output polyphonic reading device for the blind, usable by some after training to read independently a large variety of print, and the "Laser Typhlocane," a mobility aid providing the same protection as a long cane but having capabilities to examine the head-level zone out ahead for obstacles, the zone out ahead beyond an ordinary cane's reach for obstacles or landmarks, and the nature of the terrain beyond an ordinary cane's reach. Early warning indications are given of conditions in these three zones to help the blind traveler to negotiate his route safely, gracefully, and hopefully with reduced stress. The VA is currently conducting clinical application studies of these two aids and of similar devices developed elsewhere, the "Optacon," a reading aid with tactile output, and the "Binaural Sensory Aid," an ultrasonic environmental sensor used as an adjunct to a conventional long cane. Clinical trials are also underway of low-vision aids for the partially sighted such as closed circuit television (CCTV) systems.

The market for sensory aids for the blind has always been difficult to assess. Many inventors first entering the field are enthused over the apparent ease of building a sensory aid for the blind that they perceive will have major significance in alleviating some aspect of the disability. It is only with time that they begin to appreciate the difficulties which come from every part of the system. Discouragement ensues, particularly on the parts of those who may be supplying venture capital for research and development. Such capital has never been plentiful. This limitation is one reason why the VA has steadfastly, if modestly, supported several projects over the years involving both contractors and intramural activity. In addition to the devices noted above which have reached clinical application, a personal-type character recognition device and a library reading service are under development.

The VA has also long supported some hearing-aid research. With a myriad of makes and models of hearing aids on the market, there has been no dearth of venture capital in this highly competitive, commercial, and probably quite lucrative field. Basic information on acoustics and electronics and a variety of components (e.g., transistors, printed circuits, and recently integrated circuits) are also readily available. VA's research efforts with hearing aids have thus tended to leave engineering development of improved aids to the manufacturers, stimulated by

competition in the marketplace. The VA has emphasized studies to clarify the relations between the clinical value of an aid, its measurable physical properties, and the fitting methods used to select the best aid for each hearing-impaired person. VA's hearing-aid procurement system, developed over the years in part in cooperation with its research program, has had a salutary influence on the industry by pressing always for high quality but at reasonable cost. The routine use of audiology clinics to fit individual patients and a developing centralized repair program have also improved the quality of aids and services.

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RESEARCH ON HEARING-AID DESIGN

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Rehabilitative audiology is an area of primary interest in our Auditory Research Laboratory. The research we do under our contract with the Veterans Administration is one of our major efforts in this regard. We have focused both on learning what potentials and limitations hearing aids hold in everyday life and on developing techniques for determining these potentials and limitations at the time a veteran's hearing is evaluated. We have investigated various topics ranging from effects of physical performance of hearing aids on intelligibility to factors operating when the hearing-aid user is in adverse environments. Our past findings have contributed to procedures now employed by the Veterans Administration in the procurement of hearing aids and to its clinical practices in the selection of hearing aids.

Our attention was originally directed toward problems of binaural hearing-aid use. Our current research employs only monaural listening since the problem currently to be solved can be most easily attacked using monaural presentation. The application of the solution to the binaural mode will be a straightforward extension of what we thus discover.

Our present research is influenced by two basic considerations which make hearing-aid use difficult. One basic consideration is that small amounts of background noise are much more disturbing to a hearing-aid user than one would expect from the listening experiences of normal hearers. The second basic consideration is that hearing aids deliver a broad range of relatively high intensities when adjusted to bring the fainter sounds of the world to the hearing-impaired user. Under such circumstances the stronger sounds in the environment are amplified well beyond the comfortable level. The price the user pays for being able to perceive the weaker sounds of his world is that its stronger sounds are made unmercifully loud.

Our current research for the Veterans Administration seeks to minimize the effects of these two considerations by modifying the pattern of sound reproduction to gain two advantages. First, we wish the

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pattern of amplification to emphasize those components of speech which are most important to intelligibility while minimizing intense, relatively uninformative elements of speech. Second, we wish to force all sounds into a narrow dynamic range. This range will then be adjusted to be just adequately audible, thus achieving proper intelligibility. Concurrently, the intense sound elements will be kept from reaching unnecessary loudness.

A study by Thomas and Sparks suggests that a combination of filtering out lower frequencies and of clipping the peaks of the sound waves will achieve the signal needed to accomplish our goal. We are in the midst of investigations designed to discover whether this is the case.

We began the project by testing the effect of high pass filtering plus peak clipping on intelligibility as measured with the Oklahoma No. 6 test. At this preliminary stage, presentation was via a high quality conventional earphone. Each test item is a monosyllabic word. The listener knows the test word is one of four words differing only in final consonants. Every word in set of four is used with equal frequency as the test progresses, and there are five different sets of words. Both intelligibility as percent correct and specific consonantal confusions can be evaluated with this test.

The foregoing test has been administered to both normal hearers and elderly persons with presbycusis under three listening conditions: 1. high quality reproduction, 2. with the peaks of the signal clipped by 12 dB, and 3. with this same clipping plus filtering out of frequencies below 1100 Hz with 18 dB per octave slope. Broad band noise that was 10 dB weaker than the signal of the moment was present in each condition.

The study I am describing was delayed somewhat by the fact that we moved our contract research into new quarters during the year and that it took considerable time to construct, assemble, and calibrate portions of the equipment. At this writing we are just completing the testing of two groups of six subjects each. The results for these subjects of each type, expressed in terms of median scores, are shown in Table 1. We have here some evidence confirming the practical value of filtering plus clipping. Note that for both groups the filtered plus clipping conditions yielded best discrimination scores at the 10 dB and 20 dB sensation levels and that for the elderly this condition maintained its advantage at the 30 dB sensation level. Specifically for normals at the 10 dB sensation level, the clipped-filtered condition gave a median of 71.9 percent as opposed to 63.0 percent unclipped. For the elderly the absolute values were slightly lower but the advantage for clipped-filtered was greater, being 68.8 percent opposed to 59.4 percent. For each group the t test at this sensation level yielded a ratio with a probability of less than 0.05. This result leads us to interpret the differences as real.

TABLE 1.—*Median Scores in Percent*

Normals	Sensation Level		
	10	20	30
Unclipped	63.0	80.6	85.0
Clipped	67.0	78.8	86.3
Clipped-filtered	71.9	83.8	85.6
Elderly with loss			
Unclipped	59.4	71.9	78.1
Clipped	65.0	73.8	78.8
Clipped-filtered	68.8	73.8	82.5

We are still in process of analyzing the results of the foregoing study. One procedure will be to determine via confusion matrices what types of consonantal confusion predominate in the several listening conditions and for the two types of subjects.

Our next study will repeat the foregoing conditions with a three talker babble as the background. The test material will be monosyllabic words presented in triplets. Subjects will be 12 normals and 12 persons with sensorineural hearing loss. The latter will be audiologically defined as having inner ear involvement. We will retain the 12 dB clipping level. All signals will be reproduced via an insert receiver of the hearing-aid variety. Moreover, the filtering will be changed so as to yield a speech signal which is flat from 300 to 5000 Hz as defined by its spectrum level.

Provided that this filtering, plus 12 dB clipping, proves the superior condition, we will later increase the amount of clipping so as to discover the point where still further clipping causes enough deterioration in signal-to-competition ratio to affect intelligibility. Eventually, we plan also to explore the effect of variations in hearing loss upon this benefit and to look into the question as to whether tailoring of filtering and clipping for individual patients is desirable. Another important question is whether logarithmic compression is equally effective when combined with the same pattern of filtering.

In closing, I should mention that during the past year we have also been bringing several earlier projects to a conclusion. This work is being done primarily by Dr. Wayne Olsen. For one thing, he is making a retrospective analysis of the relation between the performance characteristics of 16 commerial hearing aids and our success with each instrument in the Northwestern Audiology Clinics. Secondly, he is evaluating results of a questionnaire on everyday hearing-aid experience. This questionnaire has been answered by patients from our clinics. Their experiences are being correlated with their scores on traditional tests for speech discrimination. Finally, Dr. Olsen completed a study on the

effects of head baffle and head shadow on the intensities of sounds reaching the microphones of ear-level hearing aids.

The projects I have mentioned illustrate the diversity of questions about hearing aids that we have investigated under our contract with the Veterans Administration. We anticipate similar diversity in the future.

HEARING AIDS

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There are probably less than five institutions which have produced more than two or three studies on the performance of hearing aids. The consultants who lend input to the hearing-aid program have long asked for clinical evidence that the electroacoustic measures they are depending upon to determine hearing-aid quality have relevance. Although seemingly a simple request, it is a difficult one to handle. First, we do not have clinical tests which are sufficiently sensitive to distinguish among hearing aids with different acoustic properties. Second, the technique used by clinicians to select one aid over another varies considerably, and the factor of reliability must be considered. In addition, we cannot be certain that the most significant acoustic contributor to good intelligibility is even being measured. Also, from one individual to the next, we have differences in degree of loss, slope, tolerance, discrimination function, and so on.

The program on which we are embarked, which is primarily development, has the following purposes:

1. Development and distribution of speech intelligibility materials which will better assist us in studying the relation between physical parameters of hearing aids and the users' behavorial performance.

2. Development of a practical method for measuring intermodulation distortion and transient distortion and determination of their relation to the quality of speech as processed by hearing aids.

3. Preparation of a looseleaf handbook for audiologists that will provide a complete description of the hearing aids on contract.

4. Development of seminars for VA audiologists to enhance their ability to provide rehabilitation for the hearing-impaired.

5. Development of plans for the utilization of selected audiology clinics for the collection of demographic and behavioral data, namely those related to hearing-aid performance.

6. The development of measuring techniques for aids with special characteristics.

There has been good progress on the first of these goals. Four differ-

ent types of speech materials have been recorded, and the performance of normal hearing and hearing-impaired listeners has been collected for the first test; the sentences were developed at the Central Institute for the Deaf. In fact, utilization of these sentences is being made by the Public Health Service in the National Health Survey to take place this fall. Data collection on the second of the tests, the CNC tests, has begun and is proceeding well. The second test promises to be of greater value in the assessment of hearing-aid performance. Copies of the first two tests are being made, and they will be distributed to all Veterans Administration Clinics.

With regard to the second goal, just recently we obtained the equipment necessary for measuring intermodulation and transient distortion. Therefore, work on this subject is just beginning.

Tasks three and four, preparation of a looseleaf handbook for audiologists and the seminars for VA audiologists, will require quite a bit of time and effort. At a recent chiefs' conference in Philadelphia, a 3-hour discussion on the subject of hearing aids made it quite plain that data collection utilizing our system of clinics will not be possible until we have uniformity of materials, procedures, and approach to amplification. There is complete lack of agreement among clinicians as to the procedures to be used in making a hearing-aid selection. Not only that, there is quite some disparity in the way in which they make a judgment as to the type of hearing aid a person should wear. On this latter point, it is obvious that training sessions will have to be organized for audiologists in the VA system in order that we may have some homogeneity and increased professional awareness regarding principles of hearing-aid selection. One of the first tasks, then, is education of clinicians. Toward this end, the laboratory hopes to publish a definitive description of the acoustic behavior of the hearing aids under contract this fiscal year. This will have to cover, in addition, calibration of their test equipment, techniques of fitting eyeglass-type hearing aids (especially since this is one of the most troublesome areas in hearing-aid fitting), discussion of the present coupler and the new Zwislocki coupler, the effects of earmold modification, the fabrication of instant earmolds, etc. Incidentally, the manual will contain frequency responses obtained on both couplers so that the clinicians can begin to recognize the relation between the two. Once the educational program gets underway, we can then begin to develop plans for utilization of selected clinics for the collection of data. A pilot study on 500 veterans has been useful and this coming year will be broadened considerably. The pilot study indicated that the incidence of high frequency hearing loss was much greater than we expected. As a result, we have underscored the VA need for hearing aids with high frequency emphasis.

The last goal mentioned was the development of measuring tech-

niques for aids with special characteristics. I especially have in mind hearing aids with directional properties and hearing aids with compression. Standards are not available for the measurement of their performance. We have found, for example, that there is no one single frequency at which amount of compression should be measured. Instead, it is our feeling that a low frequency, a mid-range frequency, and a high frequency will have to be utilized in order to gage the hearing aid's performance. In a sample of 15 compression hearing aids submitted to the VA we determined that only one was of sufficient quality to be placed on contract. I would like to play a tape demonstrating the range of quality present in this sample of hearing aids. (A tape is played of Peter and the Wolf). At the moment, we do not have a test battery to which the compression type of hearing aid can be submitted which will allow us to achieve an Index of Characteristics score. With a sample of ordinary behind-the-ear hearing aids, this score represents the overall quality of each aid in the distribution. It is our aim to develop this same yardstick for all aids with special characteristics.

In conclusion, I would like to affirm the laboratory's flexibility and broad range of effort in providing the kind of information necessary to maintain a hearing-aid program of high quality.

THE DEVELOPMENT OF PERSONAL READING MACHINES FOR THE BLIND

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INTRODUCTION

Mauch Laboratories research and development work on reading machines for the blind has resulted in several promising machines. The Stereotoner, which is based, in part, on the earlier Visotoner, is a new aural direct-translation reading aid. It is now being evaluated in a study using about 50 subjects. The improved Cognodictor will recognize print characters from many type styles and provide the user with the "spelled speech" sound for each letter. It uses new recognition procedures to achieve very significant performance advantages over earlier Cognodictors. A breadboard version of the Cognodictor is being built and tested. Useful accessories for the reading machines, such as the Reflex Viewer and several devices to aid tracking the lines of print have been developed.

STEREOTONER FEATURES

The Stereotoner is noteworthy for its stereophonic output code, its 10:1 zooming range which accepts letters up to 3/4 in. high, its capability for normal operation on reversed (light on dark) letters, its very small optical probe, and a compact, lightweight control box which is suspended in front of the user's chest from an adjustable neckstrap. The Stereotoner can be used for reading printed and typewritten materials including computer (and calculator) printouts. Many other tasks may be performed with the Stereotoner such as identifying paper currency denominations, reading labels on cans and boxes, determining the lightness or darkness of clothing or other objects, and locating light sources. As compared with the Optacon, the Stereotoner is one-third as

heavy, one-third as bulky, and less than one-third as expensive, yet training times and reading rates are comparable. With these and other advantages, including its wider range of letter sizes (the Optacon's magnification range is only 2.5:1) and its one hand operation, the Stereotoner will be the best choice for many people, though obviously there are needs for devices with tactile *and* audible outputs.

STEREOTONER DEVELOPMENT

A number of new ideas and several years of successful experience with the Visotoner were combined during 1971-1972 in the design of the Stereotoner. The Visotoner had been produced by modifying a tactile probe (Visotactor) by adding tone generating circuitry. Thus, a number of design features of the Visotoner were not well suited for an aural aid.

In 1970, Dr. Sanford Fidell demonstrated his use of computer generated pulses applied to each of a pair of earphones to produce the sensation of signals localized at various points inside the listener's head. This demonstration increased interest in a multicolumn Visotoner intended to produce stereophonic tone patterns representative of the portions of letter images seen by two or more columns of photocells.

Several experiments were conducted with a two-column Visotoner. These results were not promising. Later tests with a stereophonic code, produced by diverting into left and right earphones different amounts of each tone generated by a single column Visotoner, were successful. Worthwhile increases in speed and "legibility" were reported.

The design and construction of the first Stereotoner prototype was conducted during the last quarter of 1971 and the first quarter of 1972. The Stereotoner illumination system, consisting of a single lamp in a unique "clamshell" reflector, consumes only one-sixth of the power required by the Visotoner. Part of this reduction comes from the design of the reflector, part comes from illuminating a narrower vertical strip, and part comes from reducing the size of the photocells so that the image needs to be magnified less. The Stereotoner probe has a novel system of tubes containing complementary helical slots which produce its wide zooming range.

The complete Stereotoner, containing a battery which can operate it for 8 or 9 hours, weighs just 19.5 oz. The handheld optical probe which is attached to the chest box by a shielded cable contains the most frequently used adjustments for sensitivity (illumination intensity), letter size (magnification), and italic slants. It weighs only 1.5 oz. The remaining controls (switches for off-on, monaural or stereophonic output, normal or reversed print, and two volume controls (one for each ear) are located in the chest box.

With these features the first prototype was well accepted and work was

started on three additional prototypes, each one incorporating additional improvements desired in the production models of the Stereotoner. These prototypes were built and tested during the last half of 1972 and the first quarter of 1973.

STEREOTONER EVALUATION

Stereotoner production models were available in the second quarter of 1973 and a VA-NAS sponsored evaluation study, conducted by American Institutes for Research in cooperation with The Hadley School for the Blind and three VA hospitals, was started several months later. At this time all four schools are processing students and about half of the planned 48 subjects have been started in the training program. Many of the Stereotoners purchased for the study have been placed in service. Records of the required repairs indicate that making some minor design changes will result in a long interval between repairs.

Stereotoner repairs thus far have chiefly involved contact failures. A few are due to faulty solder joints; each Stereotoner contains about 500 soldered connections. More than half of the remaining contact failures were caused by a spring finger contact, which is being replaced by a soldered joint wherever possible, and the remainder were due to a bond failure of silver-filled epoxy between the battery's positive contact (a disk containing a raised post like that on a flashlight cell) and the battery's positive end. Existing batteries are being improved by removing the contact, removing the nickel plating from the bonding area, and rebonding the contact to the battery. In the future this area will not be plated.

Two repairs have involved semiconductor failures, and two probe cables have been replaced on Stereotoners which had heavy daily usage by teachers in the evaluation program. Five batteries became faulty; two of these evidently deteriorated while on the shelf for 18 months. In the future, batteries will be purchased in smaller lots to reduce the storage time.

As the Stereotoners age and receive more use, the number of battery and cable replacements probably will increase. Modifications in the cable design which may provide longer life will be tested. The number of contact failures probably will decrease as the Stereotoners are updated to remove the sources of such failures.

Mauch Laboratories will continue to service the Stereotoners used in the evaluation. The repair records and the experiences of teachers and subjects will be used to further improve the function and reliability of the Stereotoner.

COGNODICTOR FEATURES

A personal reading machine which recognizes each letter of a dozen

or more common type styles will make reading far easier and faster than possible before. To be readily available it should be compact and easily portable. It should be easy to set up and use, tolerating substantial mistracking. Such a machine should cost no more than an automobile and it should be much more reliable and maintenance free. Its usual output should be easy to learn, short, spoken letters ("spelled speech") at rates up to 100 words per minute, but provision should be made for alternate outputs such as moving braille belt displays or machine speech produced by a remote computer.

These are difficult and sometimes conflicting requirements for the Cognodictor to meet. To meet the cost requirement one must use the abilities of the operator as far as possible without placing undue burdens on him. For instance, with the addition of either an aural or tactile version of what the photocells in a hand-held probe see, the user can scan the line of print and adjust for letter size, tracking, and italic slant. With additional training the user can use these direct translation signals to recognize numerals, punctuation marks, and symbols so that the machine does not have to be made larger to accommodate these things. Even among the upper- and lower-case letters and ligatures, the user can tolerate some recognition errors so that the machine recognition system can be modestly priced as compared with commerical optical character readers.

COGNODICTOR BREADBOARD DEVELOPMENT

Although the first Cognodictor design operated well for a variety of type styles, the main problem, a requirement for tracking the line of print with deviations held to less than ±10 percent of the lower case "x" height, slowed many readers excessively. At times very rapid line scan caused both recognition errors, due to the slow response of the photo-conductive cells, and loss of letters due to the limited storage capacity of the Word Storage Unit. The fastest reader, Mr. Harvey Lauer, reported 50 words per minute; the maximum rate of the spelled-speech alphabet was 75 w.p.m.

To eliminate the tracking problem, the recognition logic and the photocell array were redesigned to use our newly invented "Two-Dimensional Multiple Snapshot Process." This process and the photocell array allow a mistracking tolerance of ±50 percent of the "x" height. Except for designing the Recognition Matrix, a breadboard version of the improved Cognodictor logic has been completed. At first, the breadboard received its input from an array of 52 photoconductive photocells pending the design and manufacture of a special array of self-scanned silicon photodiodes. In the meantime this work has been completed and one of these arrays has been installed in a Stereotoner probe for initial testing.

In the coming year a Cognodictor probe will be designed. It will probably use the base and "clamshell" reflector of the Stereotoner probe design but everything else will be redesigned for new optical reduction ratios, a new lens (two Stereotoner lenses, back-to-back), and the new photocell array of the Cognodictor probe. Also, during the coming year, a Word Storage Unit with a capacity of up to 64 characters will be designed and added to the breadboard.

The major Cognodictor development of the next year will be the design of the patterns to be used in the Recognition Matrix. These fixed patterns will be stored in integrated circuit memories and compared in sequence with each pattern produced by the Cognodictor circuitry. The latter pattern appears in the second register of the Cognodictor and it varies according to the letter last scanned.

To determine the best stored patterns, i.e., those which will achieve the highest recognition accuracy over a wide selection of frequently used type styles, a large number of second register patterns will be collected on punched paper tape. These patterns will be the results of scanning 12–15 different printed alphabets under several different conditions of tracking position and optical probe adjustment. The tape contents will be transmitted to a remote computer in a time-sharing system where a program will be used along with considerable operator input to develop the stored patterns. It is expected that three to five stored patterns will eventually be required for each character. As the development of the stored patterns progresses, the computer will be able to calculate probable recognition accuracy for each type style.

The computer will also be used to prepare a second punched paper tape which will be used to load the stored patterns into the integrated circuit memories. Sixteen integrated circuits on the breadboard can contain up to 256 such patterns, about five patterns per character. If more are needed to increase the recognition accuracy or the number of styles recognized, they can be added later.

At this time, a computer terminal with a tape punch and reader has been requested for the above uses, the writing of the computer program has been started, the circuitry to transfer the second register contents to the tape punch has been completed, and the Recognition Matrix circuitry is being wired.

For the first prototype of the Improved Cognodictor, its direct translation portion (needed for adjusting magnification, italic slant, and for line tracking) will use an acoustic optophone-like code. Two arrangements appear to be useful in reducing interference between it and the spelled-speech output. First, each ear will receive only one of the two codes through its earphone. Second, the loudness of the optophone-like code can be reduced with increasing scanning speed. Various relationships between the loudness of each code are possible and experiments in

this respect can easily be done when the first prototype is operational. If it still appears that the direct translation portion of the Cognodictor should have a tactile output instead of the aural output (either in all cases or for those people who are more tactually oriented), an array of miniature stimulators will be designed to fit one finger and stimulate its underside.

READING MACHINE ACCESSORIES

Many users of the above reading machines will prefer moving their probes freehand, especially for short periods of reading. For beginners and for extended periods of reading, a device to aid tracking the lines of print is very helpful.

For the Stereotoner, a Tracking Aid was developed. It consists of a rectangular plate, 8¼ in. long × 1 in. wide × ⅛ in. thick, with a lengthwise cutout in which an 8-in. long, ¼-in. diameter roller is mounted. Such a device can be rolled from line to line parallel to itself. During the past year, the Tracking Aid was improved by the addition of a narrow strip of magnetic material to its underside. With a steel surface, such as the dictation slide found in metal desks, the Tracking Aid will hold itself on the line while a thin, flexible paper-holding magnet which is also provided can be used along the upper edge of a single sheet of paper to hold it in place.

In order to allow a sighted teacher to see the letter "seen" by the reading machine probe, the Reflex Viewer was developed. It consists of a transparent reading surface located about 4 in. above a flat metal mirror. The illumination from the Stereotoner probe passes through the paper along with the reversed image of the letter in the lighted area. Looking from either side into the mirror, the letter can be seen in its normal orientation. The Reflex Viewer is available as a part of a Teaching Kit which also includes two Tracking Aid Clips to hold the Tracking Aid to the upper reading surface, two Secondary Earphones, and a Teaching Manual.

A new improved Colineator is also being developed. The new design will be much more compact and lower in cost while retaining the margin stops, skew adjustments, and book-handling capabilities of its predecessor.

TEACHING THE STEREOTONER; ITS PROBLEMS AND REWARDS

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Between October 1973 and June 1974, 12 blind nonveterans partici-
pated in an evaluation project on learning to read ink print with the
Stereotoner audible-output reading aid. This project was sponsored by
the Veterans Administration, in cooperation with the Committee on
Prosthetics Research and Development of the National Academy of
Sciences, which provided the Sterotoners, and the American Institutes
for Research in Palo Alto, California, which developed the training
materials. Each student had a 2- to 3-week training course, one at a time,
working 4 to 6 hours a day. The instruction was given at The Hadley
School for the Blind, Winnetka, Illinois.

BACKGROUND

There were seven men and five women in the course. All were high
school graduates, except for one senior in high school at the time of the
course. One was in his 4th year of college, seven had bachelor's degrees,
two had graduate degrees, and one had nothing beyond high school.
Eight were congenitally blind, and four became blind as children. Of the
12, two are in school, two are medical records typists, one is a program
coordinator for a small agency serving the blind, one is a musician, one is
a psychologist, and five are currently unemployed. Eight had some
knowledge of letter shapes, two were somewhat familiar with print
formats (and different kinds of print), and two had no knowledge of
print at all.

TRAINING

The training manual consists of 14 units with two to three lessons
each. The first unit deals with orientation to the equipment and tone
pattern practice. The student analyzes the tonal features of a letter
reconciling them with features of the point, like the line on the right side
of the small d. Units two through nine cover numbers and three to four

letters each. Each unit has three one-page lessons plus a criterion exercise to be administered upon completion of the unit. Unit 10 deals with the 400 most common words, self-timed reading, and letter pattern practice. Unit 11 deals with bookstyle and two different kinds of italic types, and Unit 12 deals with formats, columns, a table of contents, and a form letter. Unit 13 deals with checking one's typing in the typewriter and using the Stereotoner to identify currency. Unit 14 deals with letters likely to be confused, such as e and s. If a student had consistent trouble with the confusion of certain letters, this last unit was used. Students learned two things: how to recognize the letters by the distinguishing features of their tone patterns, and how to scan the print with the camera moved by a steady hand in a straight line. Some students had trouble hearing the horizontal bar of the small e and the line forming the bottom of the small a. Verticals, which activate more tones, such as the ascenders of the h or d, and diagonals found in the A, w, v, and y are easier to hear. This is because horizontals sound fewer tones than verticals or diagonals. Numbers are harder to learn than letters because of the similarity of the shapes found in the 5 and 6, or 8 and 0. Concentrating on the tone patterns, tracking the print, and keeping the camera moving at a good steady pace tended to make the students' hands tense. Most students learned that by relaxing their hands it was easier to keep up a good reading pace. A good stable tracking aid for beginning readers is needed so that the code is presented properly. With such an aid they would be able to concentrate more on hearing the code, less on tracking mechanics.

Of the 12 students, nine completed the training successfully and are now reading print (at least their mail) and checking their typing. Some are reading short articles. At the end of the training, they read independently, and understood how to adjust the Stereotoner for different sizes and kinds of type. Students left the training course reading from four to five words a minute. Three dropped out of the project; one had difficulty hearing the code, one had difficulty adjusting the equipment, and one could not accommodate to the intensive training, either physically or psychologically. People who have good knowledge of print-letter shapes, and good hearing discrimination, make the best Stereotoner readers. If hearing discrimination is poor, there usually is trouble picking out the distinguishing features of the letters. Without knowledge of print-letter shapes, there is difficulty relating the letter shapes to the tone patterns.

American Institutes for Research has developed four home-study units, with 12 lessons in each unit, plus a criterion exercise which must be recorded by the student for his instructor. The student says the words of the exercise while reading it with the Stereotoner. The units have tape-recorded explanations of each lesson to help him understand the format

of what he is reading. One of the nine students has completed his four home study units and one has completed three. One college student became involved in other things and did not practice. He is now reviewing in the training manual and hopefully will be sending in a recording soon. The others have not had their Stereotoner long enough to get through the units.

FUTURE PLANS

There are currently three more Stereotoners available to nonveterans. One will take training in August 1974 and one possibly in October. The possibility of teaching reading by the whole word method is being considered. Suitable texts have much repetition of words used in simple sentences. Students should learn to recognize letter and word patterns instead of reading letter by letter. New readers tend to read letter by letter; braille teachers run into the same kind of problem.

Reading print with the Stereotoner enables a blind person to do something he could not do before without sight. The satisfaction one gets by helping someone to learn to read print is indeed rewarding.

THE DEVELOPMENT OF LIVING SKILLS BY THE HANDICAPPED

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The principal task of this project at this time is the field evaluation of the Stereotoner, an optical-to-aural converter intended to enable blind veterans and civilians to read ink-print materials. The project is currently entering its second year, and collection and analysis of data on approximately 48 cases should be completed in the Spring of 1975.

As a first step, project staff prepared new training materials for use with the Stereotoner in cooperation with Messrs. Lauer and Bennett of the Veterans Administration and Miss Butow of The Hadley School for the Blind. These materials consist of a basic instructional manual comprising 14 units of study, criterion exercises, and a drill and practice tape geared to the interests and vocabulary level of adults. The content includes: Unit 1—Equipment Familiarization, Tone Practice and Tracking Techniques; Unit 2—Numerals 0 through 9; Unit 3—Letters ATRE and atre, mixed; Unit 4—Letters IHOS and ihos mixed; Unit 5—Letters DLUN and dlun mixed; Unit 6—Letters CGMF and cgmf mixed; Unit 7—Letters WPKQ and wpkq mixed; Unit 8—Letters YBV and ybv mixed; Unit 9—Letters JXZ and jxz mixed; Unit 10—Recognizing Common Words, Self-Timed Reading and Letter Patterns; Unit 11—Book Style Type, Italic Type, and Practice with Typefaces; Unit 12—Columns, Tables, and Things That Come in the Mail; Unit 13—Checking Your Equipment, Adjusting for Special Reading Conditions, and Unusual Applications; Unit 14—Remediation (Construction of Characters and Comparison of Characters).

We have also developed a second manual consisting of 48 lessons for home-study purposes. It affords newly trained persons with a guided exploration into four areas as follows: Unit A, Personal Affairs—Letters You Receive at Home, Envelopes and Mailing Labels, Postcards and Notices, Typing and the Stereotoner, Reading and Paying Bills, Computer Printed Bills, Checking Account Statement, Reading a Pamphlet and Reading Labels, Reading Cooking Instructions and Recipes; Unit B, Leisure Affairs—Magazine Tables of Contents, Reading from Magazines, Newspaper Headlines and Newspaper Articles, Reading

from TV Guide, Reading a Booklet, Reading a Catalog, Reading Record and Tape Labels, Reading from the Dictionary, and Reference Books and Indexes; Unit C, Social Affairs—Telephone Book White and Yellow Pages, Reading a Menu, Identifying Currency, Using the Stereotoner for Signing Letters and Checks, Reading Schedules and Announcements of Events, Convention Schedules, School Calendars, College Catalogs, and Reading Voting Materials; Unit D, Business Affairs—Business Letters and Memos, Forms Found in an Office, Printed Materials Around Your Office, Filling Out Forms and Application, Paychecks and Payroll Information, Printed Information About Benefits and Insurance, Computer Printout and OCR Print, Tax Withholding Forms, Property Taxes and Income Tax Short Form, and Xerox and Mimeograph Copies. Each of the four units contains criterion exercises as a check on the level of skill developed.

At the present time, instruction is proceeding at five sites. They are the three Veterans Administration Blind Rehabilitation Centers in Palo Alto, California, Hines, Illinois, and West Haven, Connecticut; The Hadley School for the Blind, Winnetka, Illinois; and the Castro Valley Unified School District, California. The latter two training stations are focusing on civilian training applications in cooperation with the Committee on Prosthetics Research and Development of the National Research Council. As of July 19, 1974, some 12 trainees had received formal tutorial training ranging from 2 to 4 weeks in duration at the Veterans Hospitals and The Hadley School for the Blind. In the study at Castro Valley, one subject, a blind school teacher, has completed initial training from a sighted instructor provided by AIR. The blind educator is now carrying on the Stereotoner training of a blind sixth grade student on a pilot basis.

All training at this time is being accomplished by blind instructors. However, our initial experience with the new reflex viewer produced by Mauch Laboratories, for use by sighted trainers, makes it appear that training by sighted instructors is viable.

Candidates for training are being identified through administration of an Auditory Selection Test. This test was designed by AIR with the counsel of the instructors involved and especially Harvey Lauer, who recorded the master. Essentially, the test consists of a stereo tape cassette with precisely reproduced Stereotoner sounds on it, accompanied by an answer sheet and directions for administration. As of July 30, 1974, AIR has scored 70 of these Auditory Selection Tests. Because of the lack of final criterion data on a sufficient number of cases, it is too soon for us to be sure of the predictive power of this test. However, we are encouraged by the initial results, and we are hopeful that we will be able to establish ranges of scores which should guide the Veterans Administration and others in properly assigning candidates to Stereotoner training.

Our evaluation procedures involve the collection of a wide variety of student characteristics at the outset of training. These include knowledge of his prior exposure to auditory codes, his hearing acuity, his intelligence, his reading preferences, and other descriptive data. We have developed instructional progress logs which should enable us to relate the amount of time studied to the output results of training, such as words per minute, accuracy, and variety of materials read. We have also developed a multipart criterion test which is to be administered at the end of the formal tutorial training period, and a second version of it which would be administered some months later, after the trainee has had full exposure to the home study units and to opportunities for private practice with the Stereotoner.

In addition, we have made followup telephone calls to trainees 1 month after training for debriefing purposes and to assess the value of the instructional materials and training procedures used. We plan to begin making home visits to a selected number of trainees in the fall after they have had sufficient time to complete the 48 lessons of their home study units and, hopefully, time to build reading speed on narrative copy. Essentially, this home visit constitutes an output criterion for the Stereotoner evaluation inasmuch as it will provide AIR staff with comprehensive information on the trainees' functional level of skill and the various uses they find for the Stereotoner.

During the fiscal year 1975, it is anticipated that further efforts will be made to recruit blind veterans as candidates for training and to open up additional opportunities for training within the civilian sector. Plans are currently underway to design a set of tapes to be used as pretraining exercises. These will allow potential trainees to gain initial exposure to the Stereotoner sounds and practice the necessary techniques involved in interpreting those sounds which they will later apply during their formal training. This is expected to alleviate, to some degree, the burden of concentrated study during a 3-week training period that presently exists.

THE CURRENT STATUS OF READING MACHINE RESEARCH AT HASKINS LABORATORIES

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At Haskins Laboratories the Veterans Administration has sponsored research with the goal of developing a high performance reading machine. The term "high performance" refers here to the combined behavior of both the reader and the machine. From the program's inception this requirement has been understood to mean that the machine *must* convert the printed text into clear intelligible English speech, so that the blind listener needs no recourse whatever to an intermediate code.

The first indications that speech, and speech alone, was the essential for high performance reading emerged from research undertaken by the Laboratories during the mid 1940's for the Committee on Sensory Devices. (This committee was established by Dr. Vannevar Bush as a part of the wartime Office of Scientific Research and Development to study potential applications of technology to alleviate the disabilities of war veterans.) Many reading devices which produced nonspeech acoustic outputs were examined and all were found to yield poor reading performances. This was despite the fact that some of the blind readers who were tested had practiced over long periods of time and were motivated to a degree that very few sighted people would be likely to match. Whether or not one subscribes to the view (as many of us at the Laboratories do) that speech is a unique code having no surrogate, the fact remains that reading machines with nonspeech output cannot provide easy, fluent access to the books that sighted people read, however useful such devices may be in more limited tasks. Learning is a chore and using them taxes the users' patience, so that ultimately they fail to meet the needs of more than a fraction of the blind.

It was for these reasons that the Veterans Administration program, revived by Dr. Eugene F. Murphy, Director of the Research Center for Prosthetics, included a project aimed at high performance. After several years of research in which many methods of generating speech were tried, a substantial portion of this objective has been reached. An operat-

ing prototype now exists in the Laboratories and various aspects of its performance are under evaluation. Results of these tests indicate that consideration should now be given to setting up a working-scale reading machine system in a large centrally located library. This pilot facility would supply subscribers with requested tape recordings of texts read by the machine, and would provide an opportunity for continued research and development to meet the problems that can be expected to arise in the early stages of any pioneering application.

The desirability of such a reading service made available countrywide is indisputable. Blinded veterans, in company with students and many other blind people who wish to take up some rewarding occupation, find themselves in need of rapid access to specialized printed information. Reading services provided by human readers, whether volunteer or paid, are invariably slow. It is not unusual for the voice recording of a new book to take several months to reach the hands of a blind subscriber. Machine spoken recordings—particularly if the publisher's typesetting tape is available—could be generated at high speed and be available to blind listeners within a few days of their request.

Here, briefly, is how we are now generating the synthetic speech that makes such a service possible. The existing laboratory prototype reader performs the conversion of typewritten text to audible speech in four main stages. Stage one is carried out by a small computer (and associated optical scanning equipment) which reads the typescript and temporarily stores the text in digital form on magnetic tape. The second stage uses a 150,000 word phonetic dictionary which is accommodated on a computer disc file. Having retrieved the text from magnetic tape, it is converted word by word from the alphabetic spelling to the corresponding phonetic spelling. The phonetic text is interspersed with small superscript marks which indicate the syllables that should receive stress and intonation symbols ($\nearrow$ and $\searrow$) which indicate the pitch contours that the computer should generate during speech synthesis. If the text contains words not found in the dictionary or lacks sufficient punctuation to achieve a satisfactory vocal output, then the third stage (manual editing) is invoked. Here a human editor views a phonetic display of the text and, with the aid of a keyboard, introduces the missing words or prosodic symbols as required. The machine then proceeds to the fourth and final stage, speech synthesis, in which the phonetic symbols are used to compute control data for a terminal analog speech synthesizer. Using a buzz source (filling the role of the human larynx), a noise source, and several dynamically controllable filters, the synthesizer is able to generate voicelike sequences of sound under computer program control which listeners hear as English speech. (Fig. 1).

Research Steps Toward
A READING MACHINE FOR THE BLIND
with Audible English Output

1. Source Text is Selected

2. Text is Read by an Optical
   Character Recognizer
   (editor corrects errors)

3. Computer (using a
   dictionary) Converts
   Text to Phonetic Spelling

4. Editor Monitors the Pro-
   cessing of Phonetic Text

5. Computer uses Phonetic
   Text to Synthesize Speech

6. Listeners Test the Intelli-
   gibility of Synthetic Speech
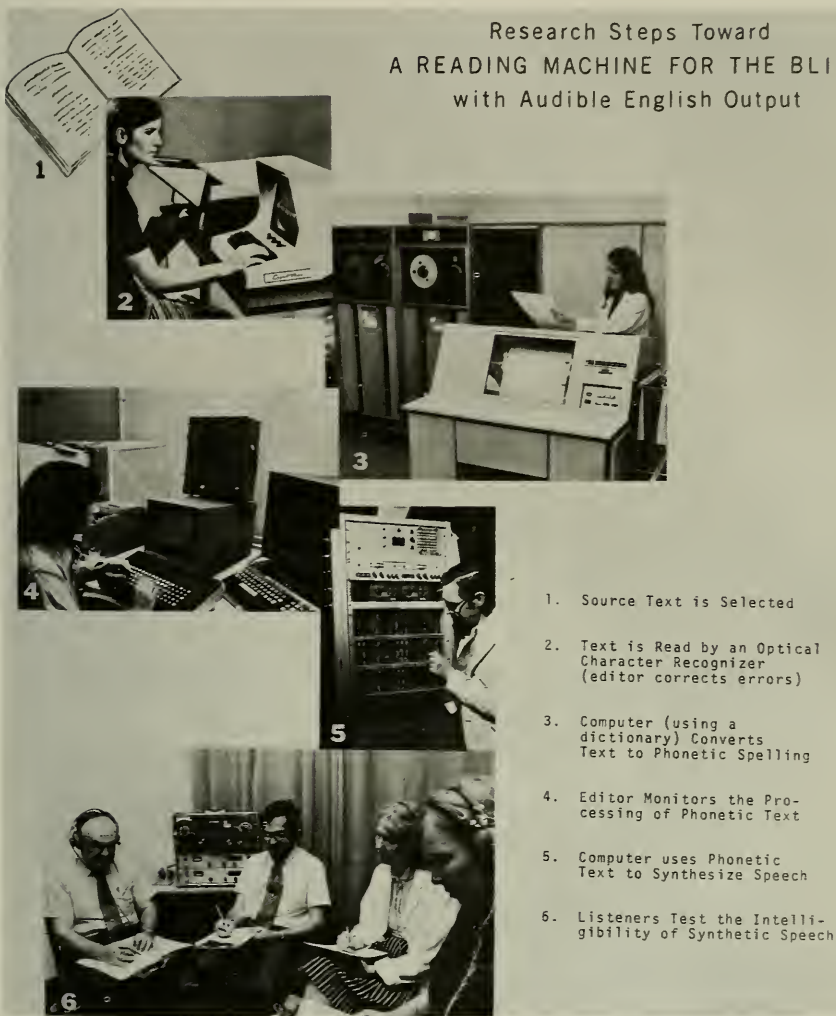
FIGURE 1

This speech is found to be highly intelligible by most people (particularly after a little practice) and yet there is no doubt that it still sounds different from human speech. We expect that, with continued research, the computer synthesis programs and speech quality will continue to improve. Even now our experience in the Laboratories with student listeners (both blind and sighted) shows that the performance of the *existing* reading machine system could provide a significant service. Our

goal is to start this service on a pilot basis while improvements to the speech and plans for broader service are underway.

The technical description of the Prototype Reading Machine system which is given here was supplemented at the conference by the presentation of a 10-minute 16-mm. sound film. Figure 2 is a page of the phonetic text used in this film. The original alphabetic input follows:

ðə · ˇbætəl · əv · ˇgɛtiz ˈbɝg · wəz · ˈfɔt
· an · ðə · ˇfɝstⱴ · ˇsɛkənd · ənd · ˇθɝd · ˈ
dez · əv · jaˇlɑɪ · ˈetinsɪksti ˇθriↃ · an
· noˇvɛmbər · ˇnɑɪntin · əv · ðə · ˇsem · ˈy
ɪrⱴ · ə · ˇpɔrʃən · əv · ðə · ˇbætəl · ˈfild ·
wəz · ˇdɛdeˈketəd · əz · ə · ˇfɑɪnəl · ˇrɛs
tɪŋ · ˈples · fər · ˈðoz · ˈhu · ˈdɑɪd · ˈðɛr
Ↄ · ðə · ˇmen · əˈdrɛs · an · ðæt · oˇkeʒən ·
wəz · ˇwʌn · əv · ˇtu · ˈɑuwərz · ɪn · ˇlɛŋθⱴ
· dəl ˈɪvərd · bɑɪ · ˇɛdwərd · ˈɛvərətⱴ · ð
ə · ˇbɛst · ˈnon · ˇɔrɑtər · əv · ðə · tɑɪmↃ · æ
ftər · ɪz · əˇdrɛsⱴ · ˇlɪŋkən · dəl ˈɪvər
d · ðə · ˈʃɔrt · spɪč · ˈnɑu · ˈso · ˇfeməsↃ

FIGURE 2.—Phonetic text used in film presented at Chicago Conference.

The battle of Gettysburg was fought on the first, second and third days of July 1863. On November 19 of the same year, a portion of the battle field was dedicated as a final resting place for those who died there. The main address on that occasion was one of two hours in length, delivered by Edward Everett, the best known orator of the time. After his address, Lincoln delivered the short speech now so famous.

THE LASER CANE

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During the past 30 years, at least 30 attempts have been made to build a useful mobility aid for the blind cane traveler (1,2). All these efforts have resulted in only three aids showing sufficient promise to warrant serious evaluation: the Kay Binaural Sensory Aid (3,4), the Lindsay Russell Pathsounder (5), and the Bionic Laser Cane. Why has the Laser Cane project been relatively more successful than so many of the others? The generalized answer to this question might help in guidance of future research in prosthetics and sensory aids — and a short history of this project may suggest an answer.

In 1945 Lawrence Cranberg (6), then a physicist at the Signal Corps Electronics Laboratory, developed a single-channel optical ranging device to be used by the blind as an obstacle detector. It was quite ingeniously designed and well constructed, judged by the standards of the 1940's. In 1948 RCA built 25 of these "Signal Corps Devices" for the Veterans Administration, who then asked Thomas A. Benham, an outstanding blind physicist and engineer on the faculty of Haverford College, to evaluate them. His evaluation report (7), made in 1952, indicated that the instrument showed promise, but before it could even be looked at more critically, several important changes had to be made.

As a result of this report, the Veterans Administration in 1953 requested Haverford College to have Professor Benham oversee the modifications required to carry out his recommendations. Haverford College, in turn, subcontracted the detail work to what is now Bionic Instruments. Thus began a long, slow, often frustrating journey, which, 10 devices and 16 years later, culminated in the first practical Laser Cane for the Blind.

The basic design criteria for an obstacle detector established by Professor Benham in 1952 have been adhered to throughout the years and have proved sound. Paraphrased, they are:

The device
1. must detect obstacles and down-curbs;
2. must be silent and unobtrusive except when giving warning;

3. must be simple to use—the user should not have to "get dressed up" in it; and

4. should perform range measurement on the principle of optical triangulation used in the Signal Corps Device.

The output of the device

5. should be tactile, if possible; and

6. if auditory, should not block other aural cues.

In 1953 transistors had not yet become readily available, so for the first few years miniature vacuum tubes had to be used, together with a few special transistors obtained directly from the laboratories that were developing them. A similar situation prevailed with regard to nickel-cadmium batteries. In addition, no practical light source except the incandescent lamp was commercially available. Thus the first few years were spent developing light sources, getting special low-noise, high-sensitivity photodetectors (first special photomultipliers, then semiconductors), and developing unusual high-efficiency electronic circuitry, typically with the generous aid of the manufacturers.

By 1962 the fifth device (the Model G-5), shown in Figure 1, had been completed and was ready for preliminary "evaluation," solely as an obstacle detector because there seemed no feasible supplement for the long cane in detection of down-curbs. In 1963 twelve G-5's were available for evaluation by the Tracor Co. Two important lessons were learned from this evaluation:

1. Though the G-5 performed adequately according to design, it did not give enough useful information to warrant the nuisance of carrying it, particularly since a cane also had to be carried in the user's other hand to detect down-curbs.

2. Not enough was known about the details of a blind traveler's strategies and performance to attempt a meaningful "evaluation" of any mobility aid except at the most elementary level.
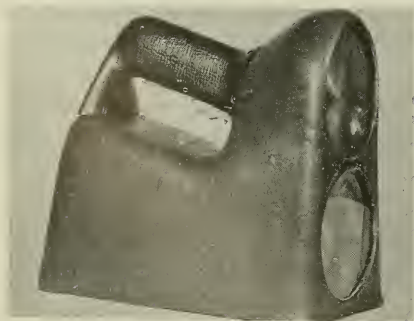
FIGURE 1.—The G-5 Obstacle Detector.

Nineteen hundred sixty-four marked the beginning of the second decade of development. Lasers had recently appeared; the efficient nickel-cadmium battery was becoming available; transistors were workaday devices, and the first solid-state light-emitting diode was soon to become available commercially. An electronic mobility aid appeared to be an idea that could be realized. Working with these remarkable new electronic devices as they took form in laboratories across the country and often before they were commercially available, we developed three prototypes of the cane we hoped would one day prove useful. (Models C-2, C-3, and C-4 are shown in Fig. 2.)

This was an exciting period for us. We had by this time acquired a feel for the range of needs of many blind travelers and for the required "state-of-the-art" that was now rapidly making it possible to meet those needs. In our attempts to establish this optimum set of design criteria we showed one "flashlight" and four successive cane models to approximately 15 institutions, 100 blind people, and perhaps 50 Orientation and Mobility Trainers for test and comment (8).

By 1971 it was judged that the Laser Cane was ready to be tried for a long period by a few seasoned cane users. An evaluation plan was developed by the National Research Council. In August of 1971 eight experienced veterans were "refreshed" and evaluated with long canes, then trained for a month at Hines and Palo Alto Veterans Administra-
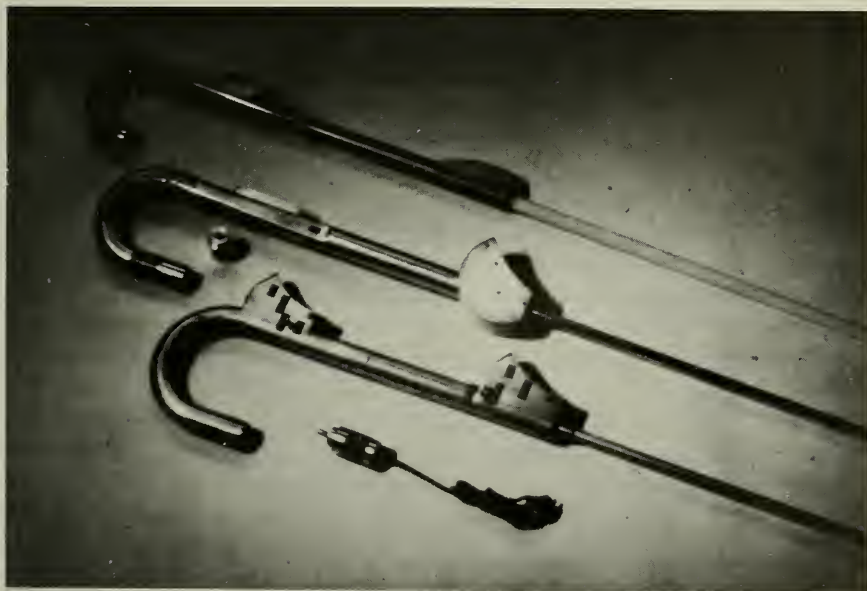
FIGURE 2.—Early models of the electronic cane. In ascending order: C-2, C-3, C-4.

tion Blind Rehabilitation Centers, and finally sent home with their laser canes. They were followed-up and systematically evaluated. A year later seven were still using their canes instead of any other travel aid (except a sighted companion), even though there was no definite statistical evidence of improved mobility in these expert travelers. Following this the Veterans Administration ordered 35 more canes so that a more significant study could be performed.

Upon receipt of this order, engineers at Bionic Instruments, Inc., once again redesigned the cane, tested a prototype with approximately 35 blind travelers, and in March 1974 delivered the 35 C-5 Laser Canes.

By now, one who has managed to read through the above historical summary may see why the project has met with a measure of success. We believe it to be for one important reason:

We tried to learn what the blind traveler really needed; and we sought to design around *this* set of specifications rather than to build what *we* thought he needed, or what technology suggested might be possible.

This was only possible because the Veterans Administration gave us enough time to go through the process outlined above. Other workers with short periods of support were not able to do this. They took a nonclinical approach. They were intrigued by the technical possibilities inherent in some physical principle, built a device based on this principle, and then found it to be unacceptable as a practical device.

Figure 3 shows the current laser cane, model C-5, which has evolved from our Research and Development Program. Figure 4 shows the C-5 laser cane being demonstrated by one of the skilled and dedicated orientation and mobility specialists, Lee Farmer, of the Hines Veterans Administration Blind Rehabilitation Center.

The C-5 Laser Cane emits pulses of infrared light which, if reflected from an object in front of it, are detected by a photodiode placed behind a receiving lens. The angle made by the diffuse reflected ray passing through the receiving lens is an indication of the distance to the object detected. This principle of optical triangulation was chosen in preference to an ultrasonic approach because of its simplicity and small beamwidth.

The Cane's output for the downward channel emits a 200-Hz tone to notify the user of dropoffs larger than 6 in. which appear approximately two paces (6 ft.) in front of the traveler. Some of the most serious of these would be downward flights of stairs, the edges of station platforms, and open manholes and cellar-ways. Down curbs, though more shallow, can also usually be detected. Proper use of the cane as a long cane, of course, provides further protection.

The straight-ahead beam, about 2 ft. above the ground, can range out to maximum distances of 5 ft. or 12 ft. from the Cane tip to a light-
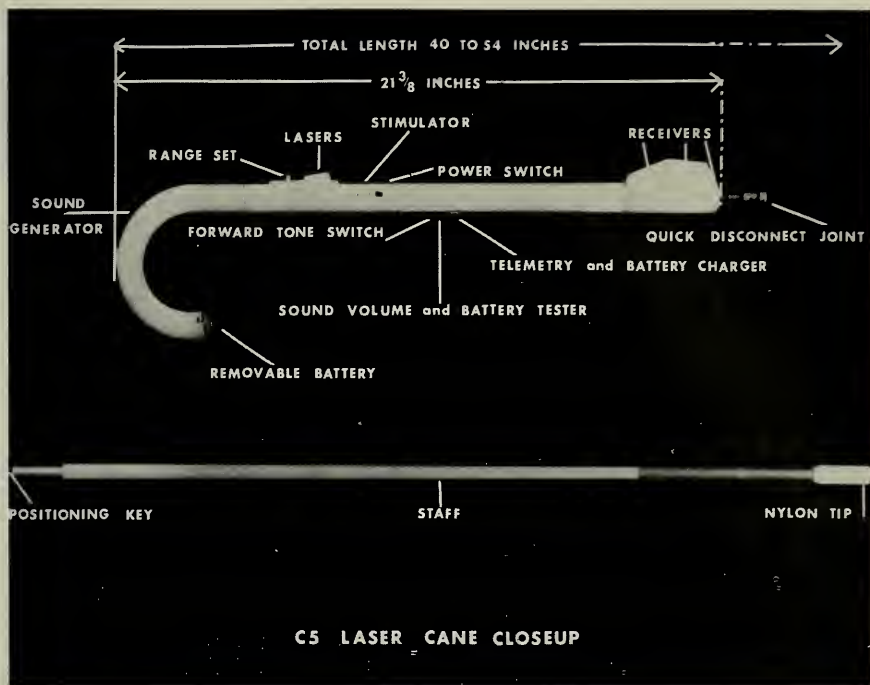
FIGURE 3.—C-5 Laser Cane.

colored target. The operating range is set by the user, who flips a switch located above the laser housing. Any obstacle detected within the selected range will actuate a stimulator that contacts the index finger when the Cane is carried in the usual long-cane manner. In addition, a 1600-Hz tone may also be switched on, if desired; e.g., when a glove is worn in cold weather.

The upward-looking beam will detect obstacles at head height appearing 1½ ft. to 2 ft. beyond the Cane tip. In preliminary studies, it was determined that earlier warnings were confusing, while this distance gave time enough to evade tree branches, signs, and awnings which the conventional long-cane traveler normally has no way of detecting. Obstacle detection is signaled by a high-pitched (2600-Hz) "beep" (see Fig. 5).

Each of the three beams is only 1 in. wide at 10 ft. so objects may be located and measured widthwise with considerable precision by suitable "fine" scanning. The normal, "course" scanning procedure is to sweep the Cane back and forth in an arc, using a modified conventional long-cane technique.

Three GaAs room-temperature injection lasers emit 0.2 microsecond pulses of 9,050 A light 40 times per second. Outputs from three receiv-

FIGURE 4.—The C-5 Laser Cane in use.

ing silicon photodiodes are each separately amplified, filtered, and coherently gated to eliminate spurious responses due to light from the sun, another Cane, or any other ambient light source, and then are used to operate the appropriate tone generator and/or stimulator. Average power consumed is 600 milliwatts from a 6-volt NiCd rechargeable battery, which operates the Cane for about 3 hours of continuous use on one charge.

Special attention has been paid to keeping the weight low (1 lb.) and to distributing it so that the Cane will approximate the "feel" of a conventional long cane. The battery, for example, is in the crook of the cane.

Five independent laboratories (9) concerned with the safety of laser radiation have studied the emissions from the three GaAs solid-state lasers used in the Cane. Two of these laboratories irradiated the eyes of rhesus monkeys for 30 minutes and for 20 seconds, respectively, with no observable effects. The other three laboratories measured laser power and calculated expected effects. All findings indicated that the Cane was nonhazardous.

More detailed technical descriptions of the C-5 Cane can be found in the literature (10, 11).
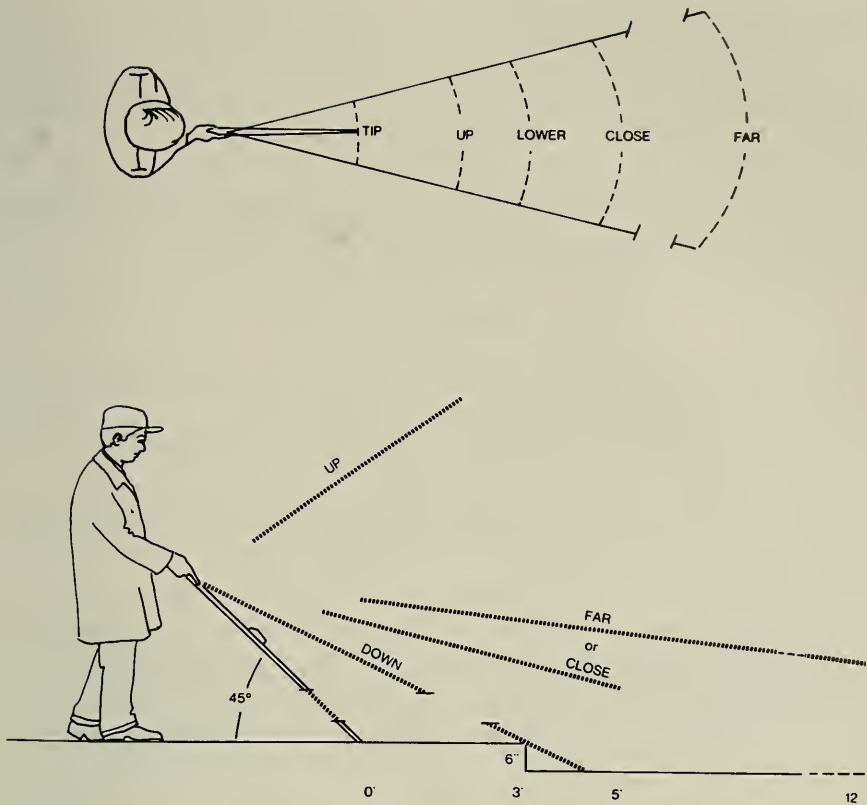
PROTECTION ZONES OF C5 CANE

FIGURE 5.—Protection zones of the C-5 Laser Cane.

Bionic Instruments is presently manufacturing 50 C-5 Canes to be delivered to the Veterans Administration early in 1975. These Canes will be distributed to a population of blinded-veteran cane travelers for continued evaluation. Bionic Instruments is also establishing a program to distribute a limited number of Canes to selected blind members of the civilian population. Persons selected will be carefully trained by accredited professional mobility instructors and followed-up over a significant period of time to determine what types of blind travelers can satisfactorily use the Laser Cane as their major travel aid.

Efforts are being made to interest the Lions and other service clubs and organizations in the financial support of the project. Since the C-5 Laser Cane is expected to cost about one-half as much as a dog guide, the Cane most likely will have to be subsidized in a similar fashion. (In

production the Cane currently costs approximately $1,950. It costs between $2,900 and $4,500 to train a dog guide and its user.)

In summary, the Laser Cane Project has progressed to the stage of limited production. Technically, the Cane itself is now considered satisfactory. Current efforts are being directed toward:

1. identifying the travelers who can best use the Cane;

2. developing a program for training Orientation and Mobility Instructors; and

3. establishing proper funding channels.

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CURRENT STATE OF THE RESEARCH EFFORT AT VETERANS ADMINISTRATION HOSPITAL, HINES, ILLINOIS [a]

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This brief report will give you an idea of what we have done, are now doing, and hope to do at Hines in the electronic print reading machines, electronic mobility aids, and low vision programs.

READING MACHINES

The electronic print reading machine was the first special program offered to blinded veterans at Hines and was the beginning of our active participation in the VA research effort on electronic devices for the blind.

About 10 years ago, Mrs. Genevieve Miller took a short course in teaching the VA-Battelle Optophone and then taught Harvey Lauer (who was a braille teacher at the time) how to use the Optophone. Mr. Lauer became very interested in the device and worked very diligently, often on his own time, to improve his knowledge of the machine and his skill in its use.

The Sixth Technical Conference on Reading Machines was held at VACO on January 27 and 28, 1966, to assist the then Prosthetic and Sensory Aids Service, Research and Development Division, in planning its research program for the future. Loyal Apple and Harvey Lauer represented Hines at this conference which was attended by scientists, engineers, and technicians whose work was related to reading machines.

At this time, it was decided that the teaching of the Optophone should not be integrated into the regular rehabilitation program but be offered as an in-patient concentrated course to selected blinded veterans possessing the aptitude, skills, and motivation necessary to learn how to use this machine. The same policy still exists today.

Since 1967, research funds have been provided enabling Harvey Lauer to work full time evaluating reading machines, developing screening tests and teaching methods, and teaching blinded persons to use the devices.

In 1967, the train-case size Battelle Optophone was replaced by the Mauch Visotoner, a smaller and more versatile instrument with the same audible code. Twenty persons received instructions and seven of these 20 became successful users of the Visotoner. Two persons were taught to use the Mauch Visotactor which gave a tactile output.

During 1971, several Visotoner users were introduced to a prototype of the Cognodictor, which is a character-recognition machine with a spelled-speech output.

The Visotoner and Visotactor were followed by the Mauch Stereotoner and the Telesensory Systems, Inc., Optacon in 1973. The Cognodictor is still in development at Mauch Laboratories.

During 8 months in 1974, Mr. Lauer instructed eight persons to use reading machines. Most stayed at Hines for 4 weeks' training including testing and several hours of preliminary exposure to both the Optacon and Stereotoner. Each person was then instructed on the device which he and Mr. Lauer felt best suited his abilities and needs. We feel that at this stage in the development of reading aids this is the only fair way to determine which type of machine is best for an individual.

Seven of the eight students are male veterans with an average age of 50 and the other one is a young woman teacher from a civilian agency. Four are using the Stereotoner and four the Optacon. All eight made slow progress; none finished the basic course materials while at Hines. Mr. Lauer had to augment the teaching materials in order for them to continue the basic course at home. One of the Optacon students has dropped out and one of the Stereotoner students, the young woman, may drop out. The remaining students are still well motivated and working diligently despite low reading rates. Mr. Lauer has been following the progress of all his students by telephone.

During the past 2 years, several speech-compressing tape recorders

have appeared on the market which will permit sighted and blind persons to increase reading rates by enabling recorded material to be played back rapidly without pitch distortion. The increased reading rate exceeds 400 words per minute. Currently these units are priced at $550 to $1,000; hopefully, further development of hardware and the commercial market should reduce the price to $200 within a few years.

We have prescribed and the VA has issued about 12 Varispeech machines to blinded veterans who are either college students or employed in jobs which require much reading. So far, we have prescribed one Cambridge VSC Cassette Recorder.

While our major effort has been concentrated on reading aids, some preliminary study has been done on such devices as improved light probes and a paper money identifier machine.

Future plans include teaching reading machines to selected students. Screening tests for the Optacon can be conducted either at the Center, or on a contract basis for those men who cannot come to the Center. The Stereotoner screening test can also be administered either at the Center or in the field.

With adequate staff we should be able to accept 20 reading machine students a year.

ELECTRONIC MOBILITY AIDS PROGRAM

The Kay-Ultra Sonic Torch was an early electronic mobility device evaluated at Hines. This was an informal evaluation conducted by several interested mobility specialists during their spare time.

A formalized mobility-aid evaluation program began in 1969 when three members of the orientation and mobility staff were selected to do preliminary studies on the C-4 Laser Cane. On a part-time basis, the instructors conducted several controlled experiments to acquaint themselves with the device. This was followed by practical work under the blindfold to test the reliability of the device and develop teaching methodology.

In 1970, with the financial support of the then Research and Development Division, Prosthetic and Sensory Aids Service, a formal Orientation and Mobility Research Program was initiated at Hines. The objectives of the program related to field testing experimental mobility aids specifically and to the overall mobility task of blind persons in general.

A C-4 Laser Cane Conference was held at Hines in September 1970. This conference was attended by persons from the VA and several public and private agencies who had worked with the 12 early cane prototypes. During the conference, it was suggested that a formal evaluation format be developed. After the conference, an advisory panel was

selected with Dr. P.W. Nye as chairman. A protocol was developed for a preliminary evaluation of eight blinded veterans by O&M research personnel at Hines and Palo Alto VA Hospitals.

The evaluation program (August 1971-November 1972) consisted of a similar 5-week training and evaluation course at each Center, with a 9-month followup program, including two visits to the veteran's home to determine how well and often he used the cane in his community. Information was gathered in the form of interviews, questionnaires, and the video-taping of the veteran's performance. During this time, the VA contracted for the production of 35 new C-5 Laser Canes.

Concurrently in 1971, the preliminary evaluation of the Binaural Sensory Aid was started. In the following year and a half, 16 blinded veterans were trained at Hines and took part in a followup program. Eight of the 16 are still using the aid.

During the last year, a continuing effort has been applied to developing teaching materials, improving evaluation procedures, and preparing for the evaluation of the production models of the Laser Cane and the Binaural Sensory Aid. We have also devoted some time to the Lindsay Russell Pathsounder, the Mowat Sensor, and the Mims Seeing Aid.

We have tried two methods of selecting candidates for the Laser Cane and Binaural Sensory Aid. We have selected veterans who had completed a basic rehabilitation program and were fairly good long-cane users who came back for a 4- or 5-week specialized program with either the Laser Cane or Binaural Sensory Aid. We also have selected veterans who are undergoing the basic training program and were introduced to the electronic device at the same time. From our limited experiences we have concluded that it is better to select candidates who have completed the basic program and acquired some travel experiences away from a center. The experienced travelers can better compare the advantages and disadvantages of the electronic devices and know what their particular mobility needs are in their own environment. This enables them to determine better whether the electronic device is beneficial or not.

The Lindsay Russell Pathsounder is a simpler device which can be incorporated in the latter stages of a basic program and does not require an extensive training period.

We plan to continue training veterans with the Laser Cane and Binaural Sensory Aid as the aids become available. We plan on gradually having all our O&M specialists become qualified teachers of the Laser Cane and Binaural Sensory Aid by attending the new Electronic Mobility Aid Course at Western Michigan University.

LOW-VISION PROGRAM

The present Low-Vision Program began in February 1972 with the

use of an optometrist to examine veterans and prescribe visual aids. Prior to this time the program consisted of evaluation of visual performance with and without hand-held aids and monoculars. The optometrist brought the knowledge of special lenses, and with his assistance a systematic and comprehensive training program evolved.

The Low-Vision Program has as its goal the optimal visual functioning of those patients who have useful residual vision. The foundation for such a program rests on the awareness that improvement in visual functioning can be obtained in the majority of those legally blind who have residual vision better than light perception and projection.

There are three phases of the Low-Vision Program: 1. evaluation, 2. optometric low-vision examination, and 3. adaptive training.

The "evaluation" begins immediately following the admission to the Blind Rehabilitation Center and is designed to determine the visual functioning abilities of the patients in daily living situations and to establish specific needs.

The "optometric low-vision examination" is performed by an optometrist specifically trained in the examination of low-vision individuals. The objective of the examination is to identify the low-vision aids which will improve the patient's visual functioning and meet his needs.

The objectives of the "adaptive training" segment are: 1. to assist the patient in understanding the visual functioning problems imposed by his visual condition, 2. to assist the patient in understanding the adjustment needed to obtain improved visual functioning, 3. to evaluate and instruct the patient in the use of prescribed lenses, aids, or illumination, 4. to resolve any difficulties encountered in utilization of aids, 5. to place the patient on exercises which will further enhance his visual functioning abilities. On understanding his unique visual functioning situation, the patient is evaluated with prescribed lenses. In most instances the optometrist recommends several lenses for each specific task. After the patient has been given time to explore fully his functioning with each lens, he makes his selection of the one(s) most beneficial.

Simultaneously with this evaluation, specific adaptive training exercises are conducted in the proper utilization of the lens, proper focal distance, movement of the head and material, plus variation of illumination settings. The focal point will vary from lens to lens and for each specific task. Therefore, it is essential that the patient not only understands the dynamics, but is able to find quickly the correct focal distance and maintain it over extended periods of time. Various exercises also allow opportunity for potential problems to emerge and be solved prior to lenses being ordered.

The type and duration of adaptive training is individualized to the patient's particular functioning abilities. Most of the exercises deal with the improvement of fixation and tracking skills for primarily near vis-

ion. Many of the patients have not read for several months or years; therefore, it is necessary to include remedial reading skills. Exercises in letter discrimination and word recognition, followed by the reading of sentences and paragraphs for speed and comprehension, are quite beneficial.

From September 1972 to May 1974, a total of 119 veterans with low-vision were examined, evaluated, and trained. Significant positive improvement was obtained in 86 percent (102) of the veterans participating. In a majority of cases the improvement was in near vision (reading). The average near-vision acuity at the time of admission was 18-point print with correction. Eighteen-point print is the equivalent of newspaper subheadlines. After completing the program, the average near-vision acuity was increased to 5-point print or the equivalent of "want ads." In 96 percent of the cases improvement was made through the use of lenses in eyeglass form or CCTV, while 4 percent were improved with hand-held aids.

In the 17 patients where no significant improvement was noted, almost half lacked the motivation for the program or possessed glasses which were adequate and upon which no significant improvement could be made.

The following categories list the veterans served and equipment ordered:

September 1, 1972–May 31, 1974

Veterans Served

A. In low-vision program
   Positive improvement 67
   No improvement 3

   | | Total | 70 |

B. In regular program
   Positive improvement 35
   No improvement 14

   | | Total | 49 |

C. In both programs
   Positive improvement 102
   No improvement 17

   | | Total | 119 |

Equipment Ordered

A. Closed circuit television... 31
B. Prescription glasses.. 150
C. Other types of aids... 105
<div align="right">Total   286</div>

In looking toward the future the Low-Vision Program will be expanded to serve veterans better. Larger clinic quarters, more optometric consultant time at the Center, and increased staff are a few of the needs of the future. Research and evaluation capabilities to deal with innovations, such as the Starlight Scope, should be established to keep current with a rapidly changing field. A sound followup program conducted by the Low-Vision Specialist should be given serious consideration. This would allow more continuing and comprehensive service to the veteran by a qualified low-vision specialist while providing needed program feedback.

CURRENT STATE OF THE VA RESEARCH EFFORT AT THE WESTERN BLIND REHABILITATION CENTER

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The year 1974 will probably be remembered as the year when the blind rehabilitation centers of the VA felt the full impact of the VA's effort to develop advanced devices for the blind. Conscientious research efforts of the past 30 years have resulted in mobility devices and reading machines which are transforming many of the standard rehabilitation center practices. The Western Blind Rehabilitation Center (WBRC) has been involved in three such sensory aids projects: electronic mobility devices, reading machines, and closed circuit television magnifiers (CCTV). Conducting these projects has led to development of a standard three-stage approach: screening, training, and followup.

ELECTRONIC MOBILITY DEVICES

Bionic Laser Cane

The WBRC was an evaluation site for the Bionic C-4 Laser Cane. The Center will be training veterans with Bionic's C-5 model beginning in July 1974.

This aid comprises electronic environment-sensing systems built into a specially constructed long cane. The user employs long-cane technique. The cane emits three laser beams that provide advance indication of overhanging and forward objects and dropoffs in the travel path.

The major screening criteria applied in selecting a veteran for the C-4 Laser Cane evaluation were: completion of training in orientation and mobility; total blindness; good health, good hearing, and no disabilities (physical or psychological) other than his blindness; location in an urban setting; good motivation, and a need and desire to travel frequently.

Two hundred fifty-five blinded veterans were considered by combing VA records, and 10 were tentatively selected. From these we were able to

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[a] Now Executive Director of the American Foundation for the Blind.

arrange the training of four.

The four blinded veterans were trained for a period of 1 month each, and all completed the training program. Video-taping over a test course was done for comparison and evaluation. All four men were issued the aids on which they were trained. We expect to maintain the training program substantially as it is.

Followups were performed and we found that three of the four continued to use the device; the fourth man did not feel that he got enough additional information to warrant using the aid. He also had a cane that broke down frequently. He is now trained to use the Binaural Sensory Aid which he prefers.

Binaural Sensory Aid

The ultrasonic Binaural Sensory Aid (BSA) is an eyeglass-mounted travel device that provides the user with early warning of objects in his travel path, and hopefully with perception of the environment, by monitoring the echoes of the ultrasonic energy the aid emits. It is used with a long cane. The WBRC has conducted evaluation of the Mark II Model of the BSA.

The major screening criteria are: no hearing loss of more than 20 decibels in either ear in the range 250-6000 Hz, completion of a course of instruction in mobility with the long cane, and no usable travel vision.

For this project 500 veterans were screened and nine selected for training. The screening process indicated that 6 percent of the veterans who completed the blind rehabilitation program could be candidates for the Binaural Sensory Aid.

The training program for the Binaural Sensory Aid extended over 1 month and comprised 30-40 hours of training. Of the nine veterans who took training, eight completed satisfactorily.

Followup consisted of telephone interviews with all nine and video-taped site visits to two users. Two use the aid on a daily basis, three use it at least weekly, three use it at least once a month, and one does not use the aid at all.

REMARKS

We have some observations on electronic mobility devices: selection should be modified to allow a broader range of men to be considered; the device appears to be mostly useful to men whose lifestyle requires they walk a minimum of several blocks each day; and finally, gaining more information of the mobility practices of the veterans appears to be critical to deployment of the aids.

Our plans for the coming year for these devices are: to train six orientation and mobility specialists to function as instructors of the devices, assist Western Michigan University in the development of a

training course for orientation and mobility instructors on electronic mobility devices for the blind, develop screening criteria for clinical purposes, which will reflect a broadening of the population range, and train selected blinded veterans in the use of one available device at a rate not to exceed an average of one per month.

ELECTRONIC READING MACHINES

Mauch Stereotoner

The WBRC is currently cooperating with American Institutes for Research (AIR) in the evaluation of the Mauch Stereotoner, a reading machine for the blind.

Plans are to train 12 blinded veterans as Stereotoner users. The screening of veterans is done by means of a prerecorded test cassette, which can be administered in a local VA office or other appropriate locations in the field. By mid-1974, 23 veterans had been screened, with 15 passing.

In selecting candidates for participation in the Stereotoner Field Evaluation Program, priority is given to veterans who show an interest and need to read moderate amounts of print on a daily basis, no significant hearing loss in the range of 440-3520 Hz, and adequate use of *at least one hand.*

The training program for the Stereotoner is 3 weeks in length. Five blinded veterans have been trained (of whom three have completed the course). Two teachers have also been trained. Followup is being carried out involving the use of print, tape recorded lessons, and tests.

Telesensory Systems Optacon

The Optacon reading machine for the blind from Telesensory Systems, Inc., is now regularly taught at the Center. It is a compact, portable reading aid for blind persons. It is about the size of a textbook, and weighs less than 4 lb. It works by converting the image of a printed character into a tactile image which a blind person can feel with one finger.

The screening of our first three veterans for the Optacon was done by the use of psychological and tactual tests through TSI. This firm has, within the past year, developed a "hands off" test for likely Optacon trainees. Fifteen such tests have been administered to veterans, and nine have been rated as acceptable candidates.

The screening criteria now being applied in this program are: inability to read ordinary print visually, passing scores or better on the Optacon screening examination, and an interest and need to manage the written word regularly.

The initial training program comprises 60 hours of instruction. *Eight* veterans have been placed in training, and *seven* have satisfactorily completed the program. In addition, three of the WBRC staff have been trained as teachers. Followup activities have been conducted through telephone contacts. It appears that *four* veterans are using the Optacon at least several times a week, while three are making minimal use of the device.

It seems that older veterans may have some difficulty in learning the codes for the reading machines and that they will require a less intense, long-term training approach. Home study material for followup or for preparation appears to be quite useful. The current screening criteria appear useful as they apply to both reading machines, but will require more validation as additional performance data become available.

Plans for the forthcoming year include the completion of the Stereotoner evaluation project and the further development of the Optacon clinical program. The home study followup material developed by AIR for the Stereotoner may enable us also to improve this aspect of our Optacon program at some future date.

CLOSED CIRCUIT TELEVISION (CCTV) MAGNIFIERS

The CCTV became generally available for clinical application in 1971. Since that time the WBRC has recommended 76 of them for use by legally blinded veterans. This instrument has provided a focal point for the development of an entire phase of this Center's program, that of visual skills.

The screening criteria for the CCTV are built into the treatment program for veterans with low vision. The criteria are: ability to read print of 1M size or smaller with the CCTV (using Sloan M units); attain a reading speed of 30 words per minute, or if one already exceeds 30 w.p.m., read 50 percent faster with the CCTV than with best near correction; ability to read for 30 consecutive minutes with the CCTV. If one can exceed this, one should be able to read 100 percent longer with the CCTV than with the best near correction; one should have the ability to address an envelope and write a letter legibly. The veteran should be able to operate the device independently for both reading and writing, involving change of focus, change of magnification, and change of polarity; he should have sufficient use of his upper limbs to permit manipulation of the equipment; and he should have an interest in and need for using the written word regularly.

The WBRC has evaluated 186 veterans for the CCTV; of these 76 were recommended. Personnel from the WBRC performed followups on 36 of the 76 veterans. These followups were made in the veterans' homes to provide any supportive services necessary as well as to deter-

mine the extent to which the equipment was used. It appeared that all equipment was in regular use. Only two pieces of equipment have been returned to the VA, and both cases involved loss of vision.

FUTURE PLANS

Plans for the future are: 1. to develop or improve training programs for visual-skills specialists and optometrists which will enable us to expand our services in this area; 2. to provide a regional service in adjustment to low vision, utilizing the current state of the art; and 3. to do research aimed at improving the visual functioning of low vision veterans.

SUMMARY

Methods for screening veterans for training on electronic mobility devices must be developed and refined in order to make proper use of the training programs. The followup for electronic mobility devices has been exemplary.

The screening test for reading machines for the blind has achieved a rather sophisticated development and can be expected to become more accurate and predictive as data are accumulated. The training programs are clearly defined and need to be modified only for older veterans. A followup for reading machines is being developed in a unique manner by AIR, and it is expected that these methods can be applied to the reading machine programs of the future.

The CCTV has been fully integrated into the clinical program and has achieved notable success as indicated by the data from thorough followups.

RESEARCH AT THE EASTERN BLIND REHABILITATION CENTER

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Through utilization of a methodology for quantitatively assessing the performance of blinded veterans in a specific acoustic environmental analysis task, various physical and psychological parameters possibly affecting the veterans' performance were examined. Because the high frequency components of human hearing are typically thought of as the most important in obstacle detection tasks, and this component is typically impaired with age, a comparison of the performance of blind-folded high school students and blinded veterans was undertaken. No significant differences in performance were found and no significant correlation between the ages of the individual veterans and their performances was seen. Pure-tone audiometric testing disclosed no significant relationship between any tested frequency and performance on the experimental task. These data and laboratory analysis of the auditory cues present in the test environment comprising sounds in the low- to mid-frequency range of human hearing, strongly imply that high frequency hearing is not a necessary condition for successful obstacle detection. This finding has important ramifications in the acoustic training of older visually impaired individuals.

A comparison of the performance data and the veteran's visual impairment, educational level, and WAIS (Wechsler Adult Intelligence Scale) verbal I.Q. indicated no significant relationships. Striking correlations between performance and MMPI (Minnesota Multiphasic Personality Inventory) and CPI (California Personality Inventory) scale scores were found. Results indicated that blinded veterans who perform better in the experimental task exhibit more adequate emotional and interpersonal adjustment. The MMPI scales related to performance were hypochondriasis, depression, hysteria, psychopathic deviate, and schizophrenia; all correlated negatively at significant levels. The CPI scales of well being and achievement via conformance and intellectual

efficiency were found to be positively correlated with performance.

A training technique was evaluated in which discrete acoustic samples, recorded with an artificial head in the actual test environment, were presented to blinded veterans in a two-alternative forced choice comparison task. A significant improvement in performance after 300 seconds of training was obtained. This training methodology will undergo further evaluation. Hopefully it will prove a valuable contribution to the area of sensory training of the blind.

A conference concerning acoustic environmental assessment and the blind is currently planned for the Fall of 1974. The intent is to have researchers from various disciplines examine the data and report on more global aspects of similar phenomena. The proceedings of this conference will be published, and if warranted, further tutorial sessions may be held. Dr. William De l'Aune will chair the meeting.

INDICATORS OF BLINDED VETERANS' CAPACITY TO USE TIME COMPRESSED SPEECH

A rationale is being developed for evaluating blinded veterans for possible issuance of time-compressed-speech devices. Veterans are tested for comprehension of the Negro Heritage Test Series at various compression rates through the use of multiple choice questions. Maximum useful compression rates obtained for each subject will then be correlated with variables such as MMPI scores, CPI scores, WAIS verbal I.Q. scores, audiological results, level of education, past history of talking book use, and major medical problems. Those listener variables having significant correlation with maximum useful compression rates will be used to construct an indicator profile for applicants for time-compressed-speech devices. Although all the data have not been collected, preliminary findings indicate that 96 percent of the veterans were able to comprehend the material at the original reading rate (194 w.p.m.), 93 percent at 1.5 × original rate (291 w.p.m.), 80 percent at 2.0 × original rate (388 w.p.m.) and 50 percent at 2.5 × original rate (485 w.p.m.). From these results it is concluded that compressed speech machines have broad applicability for use by blinded veterans. Significant relationships have also been found between maximum compression rate and scale scores on the Flexibility (Fx) and Psychological mindedness (Py) scales of the CPI. Age was also a significant variable with the younger veterans performing at a higher level. None of the other variables was found to be significantly related to performance.

RELATIONSHIP OF VELOCITY TO EXTENT OF VEER IN SIGHTLESS AMBULATION

This study was concerned with two problems. The first was

methodological in nature and involved the need for a technique to measure the extent of veer from a straight path, ongoing correction capabilities being present. The technique is for use in evaluating acoustic training procedures involving use of parallel traffic cues to improve outdoor mobility performance. Second, it has long been anecdotally noted that velocity of travel appeared to be negatively correlated with the amount of veer in sightless travel. Measurements of veer could be used to verify this anecdotal information.

Sixteen subjects, all having some experience with travel without sight, were blindfolded and asked to walk a 50-ft. straight path bounded laterally by ropes positioned at a height of 3 ft. and spaced 3½ ft. apart. The time to traverse one direction of the course and the number of rope touchings were recorded. Each subject was required to walk the route 10 times. The subjects were to align themselves with the rear wall surface before the start of each trial, and were restrained from impact with the final wall surface by a peripatologist.

A positive correlation between time of travel and number of rope touchings was found to be significant at the .01 level. This would support the previous observations that velocity of travel was inversely related to the extent of veer.

EVALUATION OF THE MOWAT SONAR SENSOR

The instrument is intended as a secondary mobility device. Pocket-sized, the hand-held device utilizes pulses of high frequency sound to detect objects. The housing vibrates when an object is within range. Frequency of vibration is determined by the distance from the object and is inversely related to this distance.

The evaluation of the device was limited because of malfunctions. The Sensor appeared inconsistent, but the source of the inconsistencies was difficult to determine because of intermittent operation. The device did not indicate the presence of a wall when its angle of incidence to the wall was more than 23 deg.

On the positive side, the small size of the device and the relative simplicity of its output information about both the direction and distance of objects should prove useful for some travelers if the problems of consistency can be resolved.

CORRELATES OF ADJUSTMENT RANKINGS BY BLIND REHABILITATION SPECIALISTS

Blind Rehabilitation Specialists from the Eastern Blind Rehabilitation Center were asked to rank randomly selected groups of 16 former clients in terms of their adjustment. Average adjustment rankings were

than analyzed for possible relationships with physical and psychological variables as well as consistency between rankers.

Initial analysis indicates that the staff rankings were very consistent. Psychological test results indicating self-sufficiency and independence appeared to exhibit the strongest relationship to average staff adjustment rankings.

PATIENT SATISFACTION WITH ADJUSTMENT-TO-BLINDNESS TRAINING

This study is an investigation of the presence and interrelationships of various aspects of patient satisfaction with adjustment-to-blindness training. A short questionnaire consisting of both multiple-choice and open-ended items will be sent to all patients who were at the Eastern Blind Rehabilitation Center 3 months or longer. Items will sample perceived adequacy of training in mobility, manual skills, communications, braille, social work and psychological services, low-vision programs, and techniques of daily living skills. Also included will be measures of overall life satisfaction, employment history, vocational training, living arrangements, extent of current blindness, as well as relative demographic data. The project will also attempt to answer a number of instructional issues, such as the usefulness of blindfold training for the partially sighted, importance of sensory training, relevancy of some traditional aspects of blind skills, and optimal length of program. The data will be analyzed in terms of responses to individual items, indices based upon a combination of questions, including the development of a global Satisfaction Index, demographic items, and the relationships between these variables. Characteristics of both highly satisfied and greatly dissatisfied patients will be noted and suggestions for procedures whereby the overall level of satisfaction might be increased will be advanced.

EVALUATION OF PARAMETERS AFFECTING SUCCESSFUL PRISM USE BY VETERANS WITH VISUAL FIELD RESTRICTIONS

The use of high-powered press-on Fresnel prism optics to displace the view of objects toward the patient's usable field of vision, so that he may detect their presence significantly sooner, is becoming more common. The purpose of this project is to evaluate various parameters possibly involved with successful prism use by visually impaired veterans. Factors such as prism power, placement of prism, lens prescription, age, sex, educational level, acuities, visual pathology, and psychological data obtained from personal histories and psychometric testing will be examined for possible relationships with functional improvements resulting from the use of prisms. These improvements will be assessed by both

objective techniques and subjective reports from the veterans using the prisms and their mobility instructors.

EVALUATION OF VARIABLES INVOLVED IN EFFECTIVE USE OF LOW-VISION AIDS BY VETERANS

An evaluation survey is being conducted to determine the effectiveness of prescribed low-vision aids once the veteran returns to his home environment. The crucial test of a low-vision clinic is the ultimate daily beneficial use of the devices offered. It is hoped that information gained from this study will provide a greater understanding of factors underlying the actual use of low-vision aids by visually impaired veterans, and will provide baseline information for evaluation of specific devices.

STUDY OF FACTORS RELATED TO EFFECTIVE USE OF ELECTRONIC READING MACHINES BY VETERANS

A correlative project, currently in progress, is investigating possible relationships between language skills, verbal I.Q., physiological skills and personality traits, and successful learning of electronic reading devices such as the Optacon and the Stereotoner. Through such knowledge more efficient screening and training of applicants are anticipated.

NORMATIVE PERSONALITY DATA FOR BLINDED VETERANS

Compilation of scores on various psychological tests (MMPI, CPI, and WAIS Verbal I.Q.) for a large number of blinded veterans is currently underway. The result should provide substantial normative data for blinded veterans, against which individual data can be more meaningfully compared.

PSYCHOLOGICAL EVALUATIONS FOR CENTRAL NERVOUS SYSTEM DYSFUNCTION IN BLINDED VETERANS

Most psychological testing for brain damage has relied on examining vision and visual motor function, systems inoperative or ineffective in persons with sight impairment. Studies by the investigator have suggested that other sensory-perceptual mechanisms can be evaluated and deficiencies in these related to brain damage. The findings may result in a scale which will yield a quantitative measure of extent of organic dysfunction in the blind.

TYPE FONT PARAMETERS AFFECTING READING DEVICE USE

An extensive survey of various publishers of magazines and books was

carried out to determine if any patterns of type-font selection could be conveyed to the users of reading devices. Various facets of the fonts in use were evaluated and teaching schemes were developed for use with students. Evaluation of the success of the techniques is currently underway.

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Special Programs

VA PROSTHETICS CENTER RESEARCH, DEVELOPMENT, AND EVALUATION PROGRAM

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INTRODUCTION

The VA Prosthetics Center Research and Development effort is organized along a time axis based on when clinically useful results from each project are expected. Each Project, supervised by a manager, may conduct research, development, and evaluation in prosthetics, orthotics or other areas. In one Project, Advanced Systems, for example, where results are not expected to reach clinical practice for several years, the scope of work includes lower-limb prosthetics, upper-limb orthotics, and spinal-cord-injury devices.

This paper has been organized to match the order of workshops scheduled for this Conference. Our work is described below in the following sequence: A. Lower-Limb Prosthetics, B. Upper-Limb Prosthetics, C. Orthotics, and D. Spinal Cord Injury.

A. LOWER-LIMB PROSTHETICS

1. VAPC Above-Knee Endoskeletal Structures

The evaluation of the "Multiplex" prosthesis through the VA Interstation Testing Program continues to point out the inadequacies of the cosmetic treatment of the above-knee endoskeletal prostheses, although the mechanical system is sound. The one-piece cosmetic cover has been temporarily replaced with the Hydra-Cadence knee cap and socket attachment plate to avoid further delay in clinical use of the Multiplex prosthesis. Several hundred models are being fabricated to phase them into production for our field distribution system.

2. Composite Endoskeletal Structures

Through a contractual arrangement with the Aircraft Division of Northrop Corp., Hawthorne, California, we are developing a plastic (graphite fiber-epoxy) composite endoskeletal prosthesis. It is in fact a fairly faithful replica of the multiplex designed to meet the Veterans Administration requirement that most fluid-knee controls, as well as a mechanical friction system, be accommodated by a single structure. It is however, lighter than the metal multiplex and may permit better dimension standardization.

3. Weber-Watkins Rotator for Lower-Limb Prostheses

Designed to permit axial rotation of the shank relative to the foot, several models of this device have been fitted to patients. Initial reactions of both the above-knee and below-knee patients were quite positive. Most reported that, they experienced more "freedom," i.e., the ability to move with less restrictions. The frequent adjustment, excessive noise, and slightly substandard cosmesis have been improved. It is now on contract. Patient reaction to the device will be monitored for a period of 1 year.

4. UC-BL Four-Bar Linkage Polycentric Knee

The University of California at Berkeley, California, has a new swing- and stance-control knee mechanism developed at the Biomechanics Laboratory by C.W. Radcliffe and L.W. Lamoreux. The stance portion of the knee is controlled by a mechanical four-bar polycentric linkage system. Swing phase is controlled by a pneumatic piston-cylinder system.

Several models are being evaluated by VA Prosthetic Center. Initial reactions of patients currently wearing them have been quite positive.

5. UC-BL Shank Torque Absorber

The VAPC is evaluating a torque absorber device for lower-limb prostheses developed by the University of California at Berkeley. This relatively lightweight, tubular design permits control of the ranges of transverse rotation and adjustment of the resistance to rotation. Fifty units have been ordered for field tests and clinical evaluations.

6. Graphite Fiber Composite Keel for SACH Feet

Models of a newly designed SACH foot keel are being fabricated for us by Northrop Aircraft Corporation of California of a lightweight graphite-epoxy composite. This material is potentially superior to wood as it is stronger, impervious to water, and dimensionally more stable. The keel is shaped better to distribute reaction force generated in the

compressible sections of the foot, an area of potential failure in conventional SACH feet. The new keel accommodates a split plug to facilitate attachment through the bottom of the foot and to permit alignment changes to be made in the foot attitude following completion of the appliance.

7. Machine Forming of Plastic Sockets

Prosthetic sockets for above-knee and below-knee are being vacuum-formed of Acrylonitrile-Butadiene-Styrene (ABS) sheets using a new portable system recently purchased from Orthomedics, Inc., of Downey, California. The plastic sheet mounted in a metal frame is heated in a conventional oven and placed, by hand, over the forming model. The advantages of this system over the commercial production vacuum systems are the comparatively small size of the unit, portability, low initial cost, and capability of the heated plastic sheet to be manipulated by hand to take advantage of the "drape" when indicated. Average molding time of approximately 10 minutes is required for forming a socket. Above-knee sockets are more easily drawn than below-knee sockets, due to the pronounced conical shape of the thigh stump. Difficulties previously encountered in maintaining critical anterior-posterior dimensions of the below-knee socket have been overcome by the use of a device which provides clamping pressures over the patellar-tendon and popliteal aspects of the socket. Suitable bonding between the plastic socket and the shank is now possible.

B. ORTHOTICS

1. ORTHO-WALK Orthosis

VAPC is evaluating this pneumatic "suit" which enables paraplegics with relatively high lesion levels to stand when the suit is inflated. Other physiological benefits are also attributed to the suit. Some 35 suits are being evaluated in seven different clinics in collaboration with CPRD. VAPC is independently evaluating an additional 30 suits using almost identical procedures.

2. Liberson Functional Electrical Stimulation

Many years ago Dr. Vladimir Liberson, now a VAPC consultant, designed an electrical nerve stimulator employing a bimodal stimulation signal train and surface electrodes for stimulating both the peroneal and tibial nerves and is expected to prevent the eversion often associated with dorsiflexion when a single electrode system is used to stimulate the peroneal alone. The required equipment is being modernized for use in clinical trials with hemiplegic patients at Castle Point, New York.

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3. Externally Powered Orthoses

Some conventional orthoses are being modified by the addition of power sources; either control switches or EMG systems. Several ball-bearing arm supports have been reworked to permit the standard VA-powered elbow to lift and lower a quadriplegic's arm. These wheelchair-mounted devices are presently being tested at Castle Point. A brachial-plexus elbow-hand orthoses that utilizes a single muscle control site to raise the arm and move the fingers is being tested.

4. Remote Manipulator

A remote manipulator with seven degrees of freedom has been de-signed. The device is wheelchair mountable and provides a sphere of operation 2½ meters in diameter, centered adjacent to either armrest. It can move a 2 kg. load through a major chord in 2 seconds. The patient controls the device either by verbal commands, by head motion, or by any residual function. The terminal device itself is similar to the VAPC powered hook, but in addition to prehension, provides the equivalent of wrist flexion-extension, adduction-abduction, and rotation. The control logic is primarily input (joystick position) to velocity. When the patient moves his head to the right the terminal device moves to the right at a velocity related to the patient's head position and independent of the previous terminal device position. Another control system which recognizes spoken speech is being fabricated. Verbal commands—up, down, slower, faster, stop, etc., will result in the desired operation. A joint NASA-VAPC effort on a continuing basis is being undertaken to advance this development. Jet Propulsion Laboratories, Pasadena, California, will coordinate the effort.

5. Polypropylene Knee Orthosis with Supra-Patellar Suspension Strap

This knee orthosis consists essentially of a calf band and a thigh band connected by knee joints. Similar to a knee cage, it employs a supra-patellar suspension strap to eliminate the need for attachment to the shoe. It provides improved cosmesis, lighter weight, and improved convenience since the shoe does not have to be altered.

C.   UPPER-LIMB PROSTHETICS

1. VAPC Free-Swing Electric Elbow

The commercially available VAPC electric elbow has been fitted with an external forearm release mechanism designed by AMBRDL. It permits the elbow to swing freely when it is fully extended and locks automatically when driven toward flexion. Both the external AMBRDL

device and the VAPC-designed internal free-swing components are being evaluated.

2. VAPC Hook

The VA-powered hook is in a final design stage. Work is underway to permit the system to operate on far smaller energy sources. Both the output prehension force and position are monitored and compared to the desired EMG information. This feedback is used to instantaneously stop the energy flow when the monitored parameter matches the EMG command. Voluntarily halting the energy flow requires hundreds of milliseconds and accounts for the major energy expenditure in these systems.

3. VAPC Hand

a. *The VA switch-controlled hand* has been modified to detect stall conditions and to automatically stop the power, thereby conserving energy.

b. *The VA EMG hand* is being modified with a feedback system similar to the VAPC hook to permit a patient to directly sense finger prehension force and finger position.

By contractual arrangement with Rancho Los Amigos, two VA hands are being modified in preparation for fitting two patients.

The hands will be *controlled* by means of standard surface *electrodes* and will provide force and position feedback by means of implanted electrodes placed against the scleral nerve. These electrodes are connected transcutaneously to the prostheses by means of the Rancho Autofeed Carbon buttons.

4. Johns Hopkins Applied Physics Laboratory Prosthesis

VAPC is evaluating six units of this electrically powered upper-limb prosthetic unit. It is designed to flex the elbow by means of a torque motor and, when the elbow is locked, to open a rubberband or spring-loaded terminal device. It is controllable either myoelectrically (three units) or by means of position transducers (three units). Fittings are being made at VAPC, Northwestern University, and Duke University.

D. SPINAL-CORD-INJURED PATIENT

VAPC has devoted a heavy portion of its total Research and Development capability to devices for the spinal-cord-injured patient. No less than nine active Research and Development projects are being conducted. A tenth project is devoted to the hemiplegic. For brevity they are classified under three major headings.

1. Mobility Aids

a. *Adaptive Automotive Equipment Standards*

VAPC is writing what we expect to be a final version of Standards and Specifications for Automotive Aids (Adaptive Equipment). These are principally hand controls to enable paraplegics and partial quadriplegics to operate automobiles and vans. These Standards are based on a year-long evaluation program of every known hand control. The evaluation included engineering analyses, simulated testing, and road testing by paralyzed veterans. This project has also led to the development of a continuous compliance testing program for these devices.

b. *Electro-Hydraulic Automotive Hand Control System*

This system is under development with controls mounted on the wheel to avoid problems of mechanical linkages to brakes and gas pedals, and to completely bypass firewall and dashboard.

c. *Hold Down System for Van Passenger in Wheelchair*

We are developing a semi-automatic mechanical locking system to safely retain a wheelchair with a passenger aboard while he is riding as a passenger in a van.

d. *Vans*

We are evaluating eight different van configurations consisting of different types of entry-exit systems and driving control systems designed for use by spinal-cord-injured patients. Driving control system, seating, entry-exit systems, and safety features are being evaluated with a view toward developing minimum standards of safety, function, and economy. Design analyses on the safety of each of these features of vans are being conducted at VAPC. In a collaborative effort the College of Engineering at Texas A&M is conducting safety and strength tests. In general the worst features of all currently available vans are the seating arrangements for both driver and passenger.

e. *Wheelchairs*

See paper presented by Ronald Lipskin appearing elsewhere in this issue of the Bulletin.

2. Environmental Control Systems

a. *Hospital Environmental Control Systems*

VAPC development of pneumatically actuated environmental control systems for hospital use is now considered complete. Several hundred units, evaluated in clinical service, have been found highly reliable and extremely effective. The basic component is commercially available.

b. *Home Environmental Control Systems*

Now under active development, the VAPC home environmental control system is fundamentally similar to the hospital type which is now

commercially available. It offers a greater number of channels for control of a somewhat different array of appliances than the hospital controller. The present model is being deployed in patients' homes where, in addition to the usual package of appliances (TV's, radios, tapes, lights, fans, etc.), it is also being used to operate front door surveillance systems, telephones, and certain reading devices. Further experience is necessary before the most appropriate set of appliances for home use can be determined.

c. *Telemetry for Environmental Controls*

Although a minor inconvenience in the hospital ward, wiring of appliances in a number of homes may interfere with decor and may present a physical hazard. But most important, the home living patient is more highly mobile than the hospital patient, and a ward-wired system required him to remain relatively static. For this reason VAPC has developed an RF link between the pneumatic actuator and the controller, eliminating the wiring. This effectively liberates the patient form the controller and all the appliances it operates. Three units are being prepared for evaluation in patients' homes. We are considering using the telemetric pneumatic actuator to control several controllers, each of which operates a different array of components in various areas of the home.

d. *Voice Actuation of Environmental Controls*

As the number and complexity of appliances and machines that a patient may operate increases and as the functions available in a particular device increase, switch-type control systems become less effective. A seven-degree of freedom manipulator, for example, is quite difficult to control by means of switches when the operator (patient) has so little information in terms of arm or hand movements. Almost all patients retain most of their speech patterns. We are therefore developing several approaches to control devices which respond to spoken speech. One project is being carried on in-house at VAPC. Another approach is being taken in collaboration with Army Medical Biomechanical Research and Development Laboratories. A third effort is being made on contract with the University of California at Santa Barbara.

e. *Scope System*

We have also taken steps to purchase the SCOPE system, which is one of the few commercially available speech recognition systems.

f. *Communication Devices*

A small number of spinal-cord-injured patients have secondary pathologies which prevent them from speaking with sufficient effect to communicate. We are evaluating several devices for nonvocal communication including the Cybertype, Possum typewriter, View Comm, etc. Experience gained during these evaluations are providing the basis for

design concepts to develop devices for use in schools and social environments. This project is not aimed at temporary loss of speech like the aphasia of the hemiplegic. It is directed more toward other neurological pathologies.

g. *Reading Machines*

Quadriplegics and others without the use of their arms are unable to read because they cannot manipulate written material. VAPC has developed a microfiche reading device which is controllable by means of the VAPC environmental controller. The unit is also independently controllable by a pneumatic switch. Also being investigated for this purpose are microfilm techniques and video tape. All of the above require processing of the written material from its original source to another form: microfiche, microfilm, and video tape. We are also sponsoring the development of a machine to enable a patient to read certain classes of written material, i.e., books, magazines, or newspapers, directly. We are considering proposals to fabricate a machine which scans by video camera written material placed on a viewing stage by an attendant. The patient, however, can control the focus of the camera, read from a bedside TV monitor, and use a page turner.

3. Patient Handling Devices

a. *Beds*

(1) We are conducting a program to evaluate various kinds of beds for spinal-cord-injured patients including the Royalaire, the Gaymar, the Stoke-Mandeville and the Hess Rotary Bed. The Nelson Bed, also being evaluated, is a device whose central portion converts into an armchair-type seat enabling the patient to sit up independently.

(2) Under *development,* at Rancho Los Amigos Hospital, is a mobile bed to enable a patient independently to reconfigure a portion of his bed into a "wheelchair" and to travel short distances depending upon the way he is dressed and the weather.

b. *Lifts*

Under evaluation are several newer types of patient lifts. The Mercy Lift fits over the entire bed, enabling a nurse or attendant to change the bed linen or to transport the patient as in a stretcher. The original unit was rather large for hospital corridors and elevators and is currently being redesigned. Also under evaluation is the Mobilizer, a device designed to enable one attendant to move a patient from the bed to a gurney or stretcher and to replace him in the bed.

c. *Cushions*

In collaboration with Dr. George Van B. Cochran, N.Y.S. Rehabilitation Hospital (now known as Helen Hayes Hospital), West Haverstraw, New York, we have developed an objective method for evaluating and

grading the utility of load-absorbing materials. An interim report recently published in BPR 10-20 details the findings on 26 cushions. These results are being validated by clinical followup prior to developing test standards.

d. *Baths*

(1) The Aurora Century Bath Lift is being evaluated in several hospitals. A patient is placed either in a wheelchair or in a contoured seat placed on a wheelchair and moved to the bath. The contoured seat, a low one for low lesion levels and a high backed version for higher lesion levels, attaches to a vertical hydraulic lift mounted on one end of the bath tub. Once the seat is firmly attached and the patient strapped in it, the attendant simply actuates the lift which raises the patient some 6 ft. in the air, rotates him 180 deg. and sets him down on a seat built into the tub. The water temperature is variable and whirlpool accessories are available. The patient is lifted out, dried, and returned to his bed.

(2) Under development is a different bath configuration in which a patient is moved, perhaps by means of a Mobilizer, to a special gurney which is rolled into a freestanding bath very much like a dishwasher. With the patient horizontal, shower heads within the unit bathe the patient whose face is protected by a curtain that hangs down around his neck. It is planned to install dry air blowers within the unit so that the patient may be dried before removal.

THE ROLE OF THE COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT AND THE COMMITTEE ON PROSTHETIC-ORTHOTIC EDUCATION

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Early in 1945, at the request of the Surgeon General of the Army, the National Research Council sponsored a conference of surgeons, engineers, physicists, and prosthetists to consider the feasibility of effecting improvements in artificial limbs. Conclusions that emerged from the conference were that virtually no organized research of significance had been conducted in the field of limb prosthetics, and that application of technology already in existence should produce improved devices.

ORGANIZATION OF RESEARCH PROGRAM

Subsequently, at the request of the Surgeon General, the NRC established the Committee on Prosthetic Devices (later the Committee on Artificial Limbs) to organize a research program. (The members of the Committee on Prosthetic Devices were: Paul E. Klopsteg, Ph.D., Chairman; Harold R. Conn, M.D.; Roy D. McClure, M.D.; Robert R. McMath, D.Sc.; Mieth Maeser; Paul B. Magnuson, M.D.; Edmond M. Wagner; and Philip D. Wilson, M.D. Consultants: Robert S. Allen and Charles F. Kettering, Sc.D.) Subcontracts were entered into with 16 universities, industrial laboratories, and foundations:

Adel Precision Products Corp., Burbank, California
Armour Research Foundation, Chicago, Illinois
C.C. Bradley and Sons, Inc., Syracuse, New York (Catranis, Inc.)
Goodyear Tire and Rubber Co., Akron, Ohio
A.J. Hosmer Corp., Los Angeles, California
International Business Machines Corp., Endicott, New York
Mellon Institute of Industrial Research, Pittsburgh, Pennsylvania
National Research and Manufacturing Co., San Diego, California

Northrop Aircraft, Inc., Hawthorne, California
Northwestern University, Evanston, Illinois
Research Institute Foundation, Detroit, Michigan
Sierra Engineering Co., Sierra Madre, California
United States Plywood Corp., New Rochelle, New York
University of California, Berkeley and San Francisco
University of California, Los Angeles
Vard, Inc., Pasadena, California

Funds were initially supplied by the Office of Scientific Research and Development. With the impending disestablishment of OSRD shortly after World War II, the Office of the Surgeon General of the Army for a short time assumed fiscal responsibility for the program. Then, for fiscal year 1947, the Army and the Veterans Administration shared the support. The Army, the Navy, and the Veterans Administration cooperated by establishing laboratories within their own organizations.

In some laboratories, development of components and application of new materials were begun, but it soon became clear to the committee that more knowledge of the patients' requirements was needed if significant progress was to be made. This in turn required a more detailed knowledge of the biomechanics of human extremities, and thus projects in this area were started. Also, anthropometric data were obtained with the idea of selecting rationally a series of standard sizes of components.

The activities of the various groups were initially coordinated by the Committee on Artificial Limbs, and considerable progress was made during the first two years. By the spring of 1947, the committee felt that it had completed its task of establishing an organized program and suggested that contracts between the government and the research laboratories be made directly, and that the committee be reconstituted as an advisory group to the sponsoring agency. At that time, the majority of service-connected amputees had been discharged from the armed forces, and their medical care had become the responsibility of the Veterans Administration. Therefore, new contracts were effected between the VA and those laboratories in which promising developments were identifiable (1947: Catranis, Inc.; Northrop Aircraft, Inc.; University of California, Berkeley and San Francisco, and Los Angeles; 1948: New York University). At the request of the VA, the NRC established the Advisory Committee on Artificial Limbs to continue the coordination and the correlation of the program. The Army, the Navy, and the VA continued to operate their own laboratories.

The general feeling at the beginning of the program was that the solution to the problem of providing better prostheses lay in developing new devices, and rapid advances were made by applying new materials and fabrication methods. It was apparent, however, that fit, suspension, and control were at least as important as components were in the suc-

cessful use of an artificial limb, and perhpas even more so. Letters of inquiry were sent by the committee early in its history to all known limb manufacturers, and one of the first subcontracts was made with the Research Institute Foundation, a laboratory operated by the Orthopedic Appliance and Limb Manufacturers Association.

In the spring of 1946, arrangements were made with certain prosthetists to fit experimental suction-socket above-knee limbs, with cooperation from local surgeons and assistance from the committee staff. Studies to establish the principles of socket configuration, fitting, and alignment were initiated as supplements to the existing projects. Both fitting and harnessing of artificial arms were studied at other projects.

PUBLIC LAW 729

In 1948, the Eightieth Congress, recognizing the need for continuity in a program of this kind, passed Public Law 729, which authorized the expenditure of $1,000,000 annually for research in limb prosthetics and sensory aids (amended by P.L. 85-56, Eighty-fifth Congress, to remove the $1,000,000 limitation). The Veterans Administration was designated as the appropriate agency for the administration of the funds, and the Administrator of Veterans Affairs was authorized and encouraged to make the results of the proposed program widely available, so that all disabled persons might benefit.

SUCTION-SOCKET "SCHOOLS"

By October 1948, experience in a number of experimental settings indicated that the suction socket provided significant advantages over other methods of fitting and suspension for above-knee amputations, and that the technique should be released for general use. Because of the many factors which enter into the successful application of the suction socket, however, the publication of a teaching manual was not considered sufficient to ensure success. Therefore, with the assistance of the Orthopedic Appliance and Limb Manufacturers Association (now the American Orthotic and Prosthetic Association) and a distinguished group of surgeons, the NRC organized a series of regional workshops to teach surgeons and prosthetists the proper application of the suction socket. The University of California at Berkeley was assigned the initial responsibility for this program. The regional workshops were continued under VA auspices with cooperation of OALMA through 1952, by which time it was felt that the suction-socket technique had become established. During the entire program, approximately 40 workshops were held.

PROSTHETICS EDUCATION PROGRAM

Through the findings of the UCLA case study and other endeavors, a considerable body of knowledge in upper-extremity prosthetics had been accumulated by 1952. Hence, the development was undertaken of a medium through which knowledge about the greatly improved devices and techniques that were available could be disseminated throughout the nation. Since the new developments involved the use of plastic laminates for all upper-limb amputation levels, the time required for thorough instruction in fabrication of prostheses ruled out the use of regional teaching sessions. The Veterans Administration therefore financed the organization and operation of the Prosthetics Education Program at the University of California at Los Angeles. Following a pilot school in 1952 for teams from the Chicago area, participation in the UCLA courses was ultimately extended to surgeons, physicians, occupational and physical therapists, and prosthetists from all over the United States. Prosthetists attended for 6 weeks; they were joined by the therapists for the last 3 weeks, and by the physicians and surgeons for the final week, during which these disciplines worked together as a clinic team.

The upper-limb courses proved to be extremely popular and very successful. During the initial, intensive phase of the program (1953-55), 12 courses were conducted. As a result of these efforts, personnel constituting 75 specialized amputee clinics, and representing 30 states and the District of Columbia, were trained. Twenty-eight of these clinics were held at Veterans Administration installations, while 47 were at other public and private institutions. Concomitant with the upper-limb education program, the VA funded a nationwide field study, conducted by New York University, to assess the value not only of specific devices but also of the treatment program taught at the schools. This study gathered much useful information and also served to reinforce the instructional material.

This combined education-research program not only served to introduce new improved concepts in the management of upper-limb amputees, but also was a tremendous stimulus to the formation of amputee clinics and clinic teams throughout the nation. Today, more than 400 amputee clinics staffed with trained personnel are in operation in the United States. This treatment concept has also spread to other countries throughout the world.

The education program at UCLA proved to be so successful that the VA sponsored the establishment of a similar education program at New York University in 1956 to meet the needs of clinic personnel. Subsequently, the Vocational Rehabilitation Administration funded an additional prosthetics school at Northwestern University in 1959. As new

devices and techniques emerged from the research program, additional courses were developed at all three schools, so that today every aspect of amputee management is covered.

PRESENT PROGRAM ORGANIZATION

By 1953, the Advisory Committee on Artificial Limbs recognized that child amputees had special problems and began to work with the Michigan Crippled Children Commission to determine what might be done to solve some of these problems. The Children's Bureau supported the establishment of several research centers, and in 1955 the committee created the Sub-committee on Child Prosthetics Problems.

From the beginning, the committee had felt that much of the experience gained in research in limb prosthetics was applicable to the field of orthopedic bracing, but it recognized that problems in orthotics were even more complex. Therefore, work was initially concentrated on prosthetics. About 1960, the Committee on Prosthetics Research and Development took steps to assist in the development of improved orthotic devices and techniques. At the present time, an active program in orthotics, supplementary and complementary to the prosthetics program, is underway.

In 1966, at the request of the Veterans Administration, CPRD formed the Subcommittee on Sensory Aids to advise the VA concerning its research program in aids to the blind.

The subcommittee also serves the Social and Rehabilitation Service in the same capacity, and recently both agencies have asked CPRD/CPOE to include problems of the hard of hearing.

Prior to 1954, most of the research, development, and education activities in prosthetics and orthotics in the United States were supported by the Veterans Administration. In 1954, Congress enacted the Vocational Rehabilitation Act, which for the first time authorized the Office of Vocational Rehabilitation (later the Vocational Rehabilitation Administration and now the Social and Rehabilitation Service of the Department of Health, Education, and Welfare) to support research and education in rehabilitation. The prosthetics and orthotics research and education programs of the VRA were initiated gradually, beginning in 1955—a significant milestone being the assumption of the fiscal responsibility for the three prosthetics schools.

Today the Veterans Administration, the Social and Rehabilitation Service, the Maternal and Child Health Service, and, to a limited extent, the National Institutes of Health, all support extramural research in these fields. The VA, the Army, and the Navy also operate research and development laboratories as part of their respective organizational endeavors.

The VA and SRS support the Committee on Prosthetics Research and Development and the Committee on Prosthetic-Orthotic Education within the National Academy of Sciences-National Research Council to correlate the various research, development, evaluation, and education endeavors supported by government and private organizations, to provide advice to various government agencies responsible for rehabilitation of the physically impaired, and to conduct a clinical evaluation program.

ORGANIZATION OF CPRD

The Committee on Prosthetics Research and Development operates within the Division of Medical Sciences of the National Research Council. The Committee's membership includes physicians, engineers, and representatives of other disciplines who are actively interested in furthering the development of prosthetic and orthotic devices and sensory aids and in the expeditious utilization of these improvements. Appointments to the Committee, normally for a 3-year period, are made by the Chairman of the Division of Medical Sciences with the approval of the President of the National Academy of Sciences.

In seeking to achieve its objectives, the Committee on Prosthetics Research and Development has, over the years, established five permanent subcommittees: The Subcommittee on Fundamental Studies, the Subcommittee on Design and Development, the Subcommittee on Evaluation, the Subcommittee on Child Prosthetics Problems, and the Subcommittee on Sensory Aids (Fig. 1)
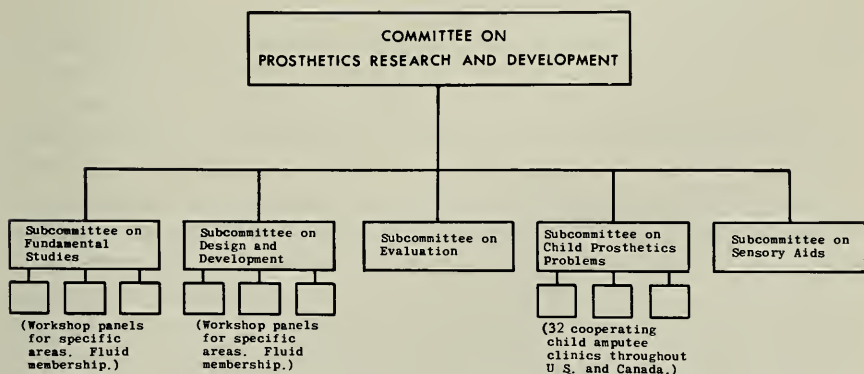

FIGURE 1.—Organization of CPRD

The *Subcommittee on Fundamental Studies* seeks to stimulate research which will provide basic information prerequisite in the design of improved prosthetic and orthotic devices. Basic research is also directed to obtaining data which will afford a better understanding of treatment processes. The subcommittee operates through small working panels which focus on specific subject areas and involve persons directly interested in and/or engaged in research in those areas. Identification and coordination of currently available information are correlative with the stimulation of research in areas where information is needed.

In pursuing its goal of encouraging and coordinating the design and development of improved prosthetic and orthotic devices, the *Subcommittee on Design and Development* arranges periodic meetings of individuals actively working in specific areas. The subcommittee promotes an active interchange of information between developers, provides leadership in attacking critical problems, provides a forum for the evaluation of new ideas and suggestions, and encourages the endeavors of competent designers. Much of the activity of the subcommittee on Design and Development is effected through so-called workshop panels. These panels now cover the entire spectrum of prosthetics and orthotics in discrete segments, *viz.*, lower-limb prosthetics, upper-limb prosthetics, lower-limb orthotics, upper-limb orthotics, and spinal orthotics.

The difficult, but essential, realm of evaluation of new and revised prosthetic and orthotic devices and techniques is a major continuing concern of the Committee on Prosthetics Research and Development. The *Subcommittee on Evaluation* encourages and coordinates an orderly effort to determine the relative merits of individual items stemming from the research and development program. The findings are passed along to the education groups and clinicians.

The *Subcommittee on Child Prosthetics Problems* provides a strong stimulus for research in prosthetics related to the juvenile amputee population and disseminates the results of this research to clinicians and others engaged in the treatment of the child amputee. Under the auspices of this subcommittee, the Cooperative Child Amputee Research Program is carried on through 32 participating treatment centers which have met standards of practice established by the subcommittee. An important medium for the exchange of information within the clinic family is the Inter-Clinic Information Bulletin which is published monthly through New York University on behalf of the subcommittee. Material for the Bulletin is assembled and edited by the Assistant Executive Director of the Committee on Prosthetics Research and Development. In response to a charge from the parent committee, the Subcommittee on Child Prosthetics Problems is now in the process of enlarging its responsibilities to include orthotic needs of the juvenile patient. In this expansion of its activities, the subcommittee is focusing its attention

initially on the orthotic requirements of children with cerebral palsy, spina bifida, and Legg-Perthes disease.

In fulfilling its role of providing advisory services to interested agencies, both governmental and private, the *Subcommittee on Sensory Aids* endeavors to keep fully informed of current activities in the development of sensory aids for the blind and partially sighted, and the deaf and hard of hearing, and to encourage and coordinate meritorious research in these areas.

The Committee on Prosthetics Research and Development/Committee on Prosthetic-Orthotic Education is served by a staff of full-time personnel employed by the Academy-Research Council. It consists of:

> A. Bennett Wilson, Jr., Executive Director
> Hector W. Kay, Assistant Executive Director
> Gustav F. Haas, Staff Engineer
> E.E. Harris, Staff Surgeon
> G.E. Sharples, Staff Officer
> Michael J. Quigley, Staff Prosthetist
> Margaret L. Young, Staff Therapist

OPERATIONAL CONCEPT

The Committee on Prosthetics Research and Development/Committee on Prosthetic-Orthotic Education endeavors to achieve its objectives in a variety of ways, depending upon the requirements and circumstances of a given project. The Committee meets twice a year or as necessary to review the recommendatons of its subcommittees and ad hoc committees. The subcommittees, whose members, like those of the parent committee, typically are appointed for a period of 3 years, also usually meet two or more times per year. Since the work of certain of the subcommittees is closely related, for example, Design and Development and Evaluation, and Design and Development and Child Prosthetics Problems, members of one subcommittee frequently attend meetings of other subcommittees.

A rewarding modus operandi in dealing with special topics or areas of interest, particularly under the Fundamental Studies and Design and Development subcommittees, has been the use of so-called workshop panels. However, the participants in the workshops are selected for their special or technical knowledge in the area under review and hence may vary from meeting to meeting. Ad hoc committees for study of special problems are also freely used. Appointments to such ad hoc committees, as is true also of the workshop panels, are not restricted to the membership of the Committee on Prosthetics Research and Development/Committee on Prosthetic-Orthotic Education. Persons with the

specialized knowledge to serve on the workshop panels and ad hoc committees are selected from a large number of qualified individuals affiliated with the Prosthetics and Orthotics Program. Personnel from the Educational Programs are included in order that the Educational Programs can be kept up to date on developments and thus effect a compression of the time required between research and education.

GOVERNMENTAL RELATIONSHIPS

Through the Academy-Research Council, CPRD/CPOE provides advisory services to the Veterans Administration and to the Social and Rehabilitation Service of the Department of Health, Education, and Welfare. Liaison representatives designated by these governmental agencies participate without vote in the deliberations of the Committee. Government laboratories cooperating with CPRD/CPOE include the Army Medical Biomechanical Research Laboratory, the Navy Prosthetics Research Laboratory, and the Veterans Administration Prosthetics Center. From time to time, individuals from these laboratories participate in the Committee's activities.

Administrative Aspects

Eugene F. Murphy, Ph.D.

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A brief discussion was held on administrative aspects.

Emphasis was placed on the need for complete and timely proposals and reports, and mention was made of the review processes in the National Academy of Sciences-National Research Council for technical matters and within the Veterans Administration Central Office for legal and fiscal aspects.

Mr. Wilson and Dr. Haas explained the CPRD's roles in evaluating proposals, making site visits, organizing and conducting conferences and workshops, publishing, and providing advice aimed at coordinating the programs of several government sponsors.

SHAPING THE FUTURE
Workshop Panel Discussions

Anthony Staros
Moderator

Director, Veterans Administration Prosthetics Center
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You have all heard the reports of the Prosthetic and Sensory Aids project leaders. It is now time to consider in more detail an administrative mechanism for dealing with each of the subjects of this conference. We have decided on a system of workshops in the several disciplines.

The Committee on Prosthetics Research and Development of the National Academy of Sciences, at the request of the Social and Rehabilitation Service of the Department of Health, Education, and Welfare, recently conducted an ad hoc committee meeting for revision of "Rehabilitation Engineering—a Plan for Continued Progress." This meeting took place in Annapolis, Maryland, June 18-20, 1974. Many of the people chairing our workshops participated in that meeting.

Therefore, I should like to ask our workshop chairmen to review the recommendations from the Annapolis meeting to determine how these recommendations apply to the Veterans Administration program. We should also like to have the workshops explore relationships among the various VA projects. At some time there should be a review to see if there is duplication of effort among projects, recognizing at the same time that there should be some systematic replication where indicated.

We want them also to consider how we can expedite the transition of items from research to development, to evaluation, to clinical use, and to education. They must also consider what high priority gaps exist in our research and development program. In this respect they should offer some definitive plans for the new fiscal year.

Their reports should be designed to provide guidance to the administrators, as well as to present and possible investigators, about projects needing our early attention. We also would urge that this mechanism be used to have investigators help fellow investigators — we hope for some productive cross fertilization of ideas. Most beneficial will be new associations among people and collaborations helpful to each of you and to the patients we serve.

Workshop Panel Discussions

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Rapporteur

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My function here as rapporteur will simply be to introduce the workshop panel chairmen who will summarize the substantive developments at their workshops. Additionally it should be recorded that from an impromptu survey of the attendees, the majority felt that a meeting of this kind should be held approximately once every 2 years.

LOWER-LIMB PROSTHETICS WORKSHOP

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INTRODUCTION

This report is a summary of the panel's views on the recommendations of a recent CPRD-sponsored conference at Annapolis, Maryland, June 19-20, 1974, plus the additional views expressed in the Panel on Lower-Limb Prosthetics.

Clinical problems at each amputation level were discussed, problems identified, followed by recommendations for either continuing present programs or initiating new Research and Development efforts.

Topics of a more general nature were also discussed, the conclusions of which may be found in the concluding section under the heading "General Recommendations."

PARTIAL FOOT

For partial foot amputations proximal to the transmetatarsals (including the Chopart and Lisfranc), there are problems of painful distal scars and abrasions, lack of shoe space to incorporate adequate prosthesis, painful ankle joints, and poor resulting cosmetic effect, all of which often present management problems to the clinic team.

Elective amputations between the levels of transmetatarsals and Syme are to be discouraged for reasons of poor prosthetic results. Development effort should be directed toward the design of a partial foot prosthesis that will reduce the distal stump loading, possibly through simulating a plantar-dorsiflexion motion.

SYME

Clinically there are still a small percentage of Syme's amputees with

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[a] Chairman of the workshop.

painful stumps. Even nonpainful stumps are bulbous and often create a poor prosthetic result, particularly with regards to cosmesis, and in some cases durability.

Clinical experience with reducing the medial-lateral dimension of the Syme stump by trimming the malleoli should be reviewed and evaluated to determine the merits of this procedure in improving the prosthetic result.

Any surgical technique which successfully presents pain-free narrower stumps should be given greater dissemination through recognized educational programs.

Continuing effort should be made to introduce new highstrength low-weight materials to produce lighter and more cosmetic Syme prostheses.

The expandable inner-socket of the insert technique is an acceptable alternative to provide suspension of the Syme prosthesis. Training manuals illustrating fabrication techniques should be prepared.

Development effort should be directed towards the design of a prosthetic device that allows controlled articulation at the ankle joint level.

FEET AND ANKLES

SACH Foot

SACH feet are being fitted incorrectly, resulting in poor function. Problems of durability arise when molded SACH feet must be reshaped to function properly in standard shoes. There is a lack of standardization throughout the industry on foot shape, heel height, and location of bolt attachment. The current method of attachment of the SACH foot to tubular pylons is inadequate in many cases.

Continued development of the SACH foot should be encouraged with particular emphasis on use with the endoskeltal systems. Standardized attachment geometry should be adopted for all new feet. It should clearly be recognized that SACH feet for above-knee prostheses require different characteristics from those for below-knee prostheses.

Existing information on the proper application of the SACH foot should be made more readily available to clinical personnel.

Articulated Ankles

Conditions of irregular terrain present the need for articulated ankle function. A high priority should be given to the clinical introduction of the Mauch hydraulic ankle.

Existing feet with articulated ankles should be available for use with endoskeletal systems.

BELOW-KNEE PROSTHESES

Components

Although the current clinical practice of fitting the PTB total contact prosthesis with a SACH foot and woodlaminated shank presents few serious problems, there are the following shortcomings:

1. The time and associated expense required by the transferring techniques for subsequent socket changes necessary due to changes in stump volume caused by either stump atrophy or hypertrophy.

2. The need for materials providing greater versatility in socket fabrication techniques.

Continuing emphasis should be placed on the refining of present below-knee endoskeletal designs with particular emphasis on:

1. Maintaining the option of retaining the adjustable alignment unit or replacing it by transfer to nonadjustable pylon or conventional limb.

2. Reducing weight and increasing the durability of components.

3. Providing a waterproof prosthesis.

4. Providing noiseless foot attachment couplings with the minimum external diameter.

Socket Design

Although the PTB with its variants has been generally successful, some problems still persist in the fitting of patients with peripheral-vascular disease. Clinical results continue to support the general use of immediate and early fitting procedures followed by the application of total contact sockets.

Suspension

In spite of the array of suspension alterations for the PTB and its variants, problems related to inadequate suspension still persist in certain cases. Continued developments should be encouraged in methods of improving limb suspension, such as using alternating fluid chambers, suction sockets, or possibly muscle bulge.

Recent clinical findings indicate that thigh corset suspension used over a long period of time may contribute to localized peripheral-vascular disease. A *high priority* should be given to the screening of patients with prolonged use of thigh corset suspension in order to detect the possible presence of circulatory restriction.

Continued emphasis should be directed toward the development of transcutaneous skeletal attachment for limb suspension.

Cosmesis

The most pressing problem preventing the widespread use of the endoskeletal system is the lack of an acceptable cosmetic covering.

It is *highly recommended* that a workshop be organized to review and clearly define the requirements for cosmetic restoration and fully discuss thoee needs with materials specialists. Dr. John F. Lontz indicated a willingness to assist in making contact with several representatives of the chemical and prosthetic industry and research institutes. This meeting should result in a request for proposals which could possibly deal with several aspects of the problems.

KNEE DISARTICULATION

In spite of the recent introduction of the OHC (Orthopedic Hospital-Copenhagen) 4-bar unit, problems still exist which require continuing development. These are related to:

1. A need for improved knee function.
2. Poor cosmesis, especially for females.
3. Excessive length of the unit.

However, the clinical community should be informed that improved devices are now available for the knee-disarticulation amputee, so that amputation at this level need not be rejected solely on prosthetic grounds.

ABOVE-KNEE PROSTHESES

Components

Many knee devices which could provide functional benefits to selected patients are not being provided to VA and civilian amputees on a wide basis, apparently for reasons of economics.

It is strongly recommended that new financing procedures for new components be devised to insure that the higher cost of high performance swing-control devices will not prohibit their use.

There should be continuing development and effort toward a knee unit which will allow continuous voluntary control of various knee resistances using EMG or some other control input.

Effort should be encouraged toward the development of lightweight, low cost, endoskeletal above-knee prostheses. An acceptable lightweight, low cost, endoskeletal prosthesis does not at present exist for the geriatric amputee.

Suspension and Cosmesis

Improved suspension techniques for the above-knee socket should be developed, possibly employing mechanical concepts such as the "Chinese Finger Trap," unidirectional fibers, or high friction materials, with particular reference to the needs of the geriatric amputee.

Development should continue on the desirable objective of a one-piece cosmetic cover, in addition to continuing the work of improving two-piece covers.

HIP-DISARTICULATION

No clearly defined procedures for casting and fabrication of the hip-disarticulation socket are currently available.

Existing techniques of hip-disarticulation casting should be reviewed and evaluated with the purpose of determining the most satisfactory approach.

Development of a coordinated hip-knee-ankle prosthesis with hip and knee swing control is recommended.

GENERAL RECOMMENDATIONS

Evaluation

Full advantage should be taken of the increasing capabilities of developing multi-disciplinary clinics for conducting expanded evaluation programs with patients using new devices and techniques within the VA system.

Standards

It is recommended that the following two equivalent sizes of aluminum tubing be adopted as standard sizes for adult endoskeletal prostheses.

1. 35 mm. o.d., × 1.6 mm. wall.
2. 1-⅜ in. o.d., × ¹/₁₆ in. wall.

It is recommended that attachment of artificial feet to tubular pylons be made with internal coupling devices to provide a slender structure at the ankle in order to allow easy removal of the foot.

It is recommended that the VA support the current efforts of ISPO to introduce international standards in lower-limb prosthetics.

Biomechanical Studies

Future gait studies involving lower-limb amputees should be closely coordinated with efforts of the CPRD Task Force on clinical gait evaluation.

Evaluation of Patients with Peripheral Vascular Disease

Within the VA patient population and the civilian community, there is

an increasing incidence of amputation due to peripheral vascular disease.

It is recommended that more widespread use be made of currently available vascular evaluation techniques for long-term surveillance of high vascular risk populations. These would include patients with diabetes and hypertension and, in particular, below-knee amputees who have worn thigh corset suspensions for many years.

The objectives of such a program would be a reduction in number and a retention of lower levels of amputations through:

1. Early recognition of vascular disease.
2. Early treatment.
3. Continued closer surveillance after treatment.

Because of the technology involved, close cooperation is required between vascular surgeons and bioengineers.

ORTHOTICS WORKSHOP

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INTRODUCTION

The members of this Workshop, although few in number, represented the various disciplines concerned and expressed independent opinions. They were present throughout the Workshop, with the exception of Dr. Schmeisser who was a welcome addition to the discussion on upper-limb orthotics.

The Workshop accepted the definition in *Stedman's Medical Dictionary*, which is also used in the new terminology, that an "orthosis is a medical device applied to or around a bodily segment in the care of physical impairment or disability." They considered that it is limited to devices attached to the body and does not include mechanisms fixed to mobility aids, beds, etc.

They considered that the reluctance of patients to use a prescribed orthosis indicates a need for Research and Development in this field in which the numbers in need would provide an effective return for the cost.

The Workshop noted that in the conference there were only two papers devoted to orthotics and a passing reference in three other papers. The Workshop itself had attracted few participants who were expected to cover the varied orthotic management of a multiplicity of diseases in the three areas of upper limb, spine, and lower limb, whereas prosthetics had separate workshops for upper and lower limbs and had no need for spinal prosthetics. They considered that this reflected widespread apathy towards orthotics.

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[a]Chairman of the workshop.

The Workshop wished to record its acknowledgment of the major contributions which have been made by the Veterans Administration Research Center for Prosthetics and the Veterans Administration Prosthetics Center, New York, to the design and development of new orthoses.

The Workshop made a systematic review beginning with the lower limb distally and moving proximally, then to the spine and finally the upper limb. At each level, an attempt was made to establish the state of knowledge in certain categories, namely biomechanics and patho-mechanics, the actual rather than alleged mechanical effect of orthoses including over-bracing, comfort and cosmesis, materials, and post-graduate education.

It soon became evident that there were conclusions and recommendations which were common to all levels as well as a number related to specific areas.

GENERAL

Orthotic treatment requires an analysis of the pathomechanical deficit of the patient, a prescription of the mechanical characteristics required from the orthosis, and a structure which in design and materials is durable, comfortable, and of an appearance accepted by the patient. It also requires education in orthotics principles and practice of all concerned.

The American Academy of Orthopaedic Surgeons' Technical Analysis Forms, devised by a committee chaired by Dr. Newton C. McCollough, III, provide a system in which to record the static but not the dynamic deficit. The Orthotic Terminology developed by the Committees on Prosthetic-Orthotic Education and Prosthetics Research and Development of the National Academy of Sciences, under the chairmanship of Dr. Jacquelin Perry, gives a means of describing precisely the mechanical and structural character of an orthosis, and the revised American Academy of Orthopaedic Surgeons' *Orthopaedic Appliances Atlas,* which should be available around January 1976, will give a comprehensive reference of those available.

The Workshop considered that at no level in the lower limb or spine was there an adequate knowledge of or means of establishing or recording the dynamic pathomechanics. They also considered that the upper limb, which had been better studied, still needed further research.

The Workshop also considered that too little is known of the real as opposed to the alleged biomechanical effects of orthoses on patients. This also applied to unwanted over-bracing.

It was the opinion of the Workshop that the introduction of new materials was haphazard and largely dependent on fortuitous observation. It is considered that there are a number of organizations or agencies which have professional staff regularly perusing technical journals who might index new materials which appear to be suitable for orthotics or prosthetics use so that their potentials can be studied and even be tested. Such centers could then supply information about available materials to workers in research and development.

The panel was of the opinion that new orthoses, even those which have been evaluated and are taught in the schools, are not supplied in the field to patients. It noted the very considerable efforts being made by the Veterans Administration, the American Academy of Orthopaedic Surgeons, the university orthotics and prosthetics teaching schools, the American Orthotic and Prosthetic Association, and the American Academy of Orthotists and Prosthetists to give graduate education. It was thought that the total response was woefully inadequate. While all disciplines are at fault, it was thought that the key to this was with the physicians who prescribe orthoses. It was considered that prescribing physicians might be required to attend specific courses in orthotics as are the physicians in charge of amputee clinics. It is realized that many veterans are accustomed and inured to their established orthosis and will have no motivation to change.

The panel discussed modularity and cosmesis which are not necessarily antagonists. Modularity was considered to have advantages in short-term, immediate or rapid fitting, and for this, cosmesis can be of secondary importance. For long-term use, cosmesis was considered important for patient acceptance and use. For this, modularity may need to be sacrificed for custom fabrication. Cosmesis in an orthosis was not defined, but it was considered that orthotic cosmesis should not be equated with prosthetic cosmesis where there is a need to restore the body image. It was agreed that preferably an orthosis should be invisible but that when this is not possible, it should be an embellishment.

Little time was given to emergency or temporary orthoses. The Workshop is concerned that too often when an emergency orthosis, which is maintaining a clinically good position, is removed so that a temporary orthosis may be applied, there is a deterioration in the position. It was suggested that research be directed toward developing materials or systems which can be used for emergency and also be left undisturbed as the temporary orthosis with or without some addition.

SUMMARY

To summarize, the Workshop made the following general recommendations:

1. That there be greater proportional and actual funding for research and development in orthotics.

2. That knowledge of the dynamic pathomechanics of the lower limb and spine be collated and research be directed to further study.

3. That knowledge of the actual biomechanics of current orthoses be collated and that support be given to research to establish the effectiveness and identify the unwanted actions of others.

4. That one or more agencies or organizations with professional staff should establish a formal system to cull technical literature for new materials so that this information may be available for research and development.

5. That the current effort to provide graduate education in orthotics should be intensified and that consideration be given to requiring physicians and/or orthotists to have formal instruction in modern orthotics principles and practice if they are to prescribe and supply orthoses to veterans.

6. It is recommended that, in orthotic design, consideration be given to modularity and cosmesis.

7. It is recommended that research be directed to new systems and materials for use in emergency and temporary orthotic management.

Specific Levels

Lower Limb

a. Foot Orthoses (FO's)

The panel was aware of their own ignorance of the pathomechanics of the foot and also of the mechanics of many well-tried foot orthoses. They wish to draw attention to the American Foot Society which may well have a fund of useful knowledge in this area.

The Workshop thought that the new materials now available have improved the possibilities of meeting the mechanical needs when these are known. Currently, much of the treatment, although effective, is empirical in use.

The Workshop notes that current VA regulations inhibit the adequate orthotic treatment of many foot pathologies.

b. Ankle-Foot Orthoses (AFO's)

The panel noted the Annapolis report. They agree with it that knowledge of the new orthoses needs dissemination. They were not satisfied that their mechanical characteristics were fully known, nor that the materials currently used are the best available for the design.

c. Knee Orthoses (KO's)

Doubts were expressed about the alleged control by knee orthoses to prevent hyperextension of the knee. In this section, the knee-ankle orthosis with floor reaction was also considered. This was an area in particular where the general recommendations on biomechanical research was considered pertinent.

d. Knee-Ankle Orthoses (KAO's)

There are many new designs and new materials being used for these orthoses. Their design depends upon the implementation of the general recommendations. The Workshop did consider that consideration should be given to design of new joints and of control mechanisms. In the near future, swing- and stance-phase mechanisms might be desirable for certain categories of patients. The Workshop saw no need for a major effort in external power systems as yet but considered that they should not be ignored.

e. Hip-Knee-Ankle Orthoses (HKAO's)

The Workshop considered that attachment of a lower-limb orthosis to a spinal orthosis was usually detrimental and over-bracing, and that hip control was usually better independent of the spinal system.

They also considered that a study of hip-unloading orthoses and abductor orthoses is needed to establish their alleged mechanical effects.

The current evaluation of the pneumatic thoraco-lumbo-sacral-hip-knee-ankle orthosis (TLSHKAO) by CPRD for VA was noted. The Workshop thought that, if this proved satisfactory, consideration should be given to the development of other orthoses using inflated struts for stability.

Spinal Orthoses

a. Cervical Orthoses

There was considerable divergence of opinion on the use of cervical orthoses. It was agreed that the mechanical control, if any, was minimal. It was thought by some that they were clinically effective. There seems a need to establish factually what mechanical effect, if any, these CO's have, for they are either an example of unnecessary over-bracing or their clinical use and limitations should be confirmed.

b. Cervico-Thoracic Orthoses

The Workshop was of the opinion that control of the cervical spine required extension onto the upper thorax and onto the cranium. These orthoses particularly need cosmetic design in the broadest sense. They are:

1. Lumbo-Sacral Orthoses (LSO's)
2. Thoraco-Lumbar-Sacral Orthoses (TLSO's)
3. Cervico-Thoraco-Lumbar-Sacral Orthoses (CTLSO's)

There have been a number of studies of the mechanics of the spine, many of which are unrelated. The panel thought that the biomechanics and pathomechanics of the spine in all its varieties was poorly known but that in part this might be due to a lack of dissemination. It recommended that the current available knowledge be collated and that a planned study of unknown factors should then be attempted. It was noted that low back pain, its cause and treatment, is still a major cause of disability despite the volume of work on it.

Upper Limb

Time limited the discussion on the upper limb. The Workshop considered the pathomechanics of the upper limb to be better known than other parts, due largely to the work of the various national hand societies.

Nevertheless, the need to educate physicians into the current orthotics possibilities was emphasized.

Attention was drawn to the current acceptance of the three-point chuck grip as the only grip. Its universal use was questioned. The Workshop considered that a search might be made into the literature of hand function so that reconsideration be given to the optimum position of the hand. It was noted that in North America and Britain lateral grip and hook were the accepted modes, and it was thought that their use in orthotics should be considered.

The panel agreed that body power should be used in dynamic orthoses but also thought that external power should be used to supplement or replace diminished or lost function. They saw no reason to restrict development to one power source. Cross-fertilization from the prosthetics program should be encouraged but is limited. Control sites and systems are suitable for both, but the current trend in prosthetics for integral actuators cannot be applied to orthoses. Currently, there are gas-powered McKibben actuators used in orthotics which have proven unsatisfactory in prosthetics, and the possible use of the Heidelberg actuator in orthotics. The Johns Hopkins' actuator was the only electrical actuator known to the Workshop suitable for orthotics use. They

consider that consideration should be given to designing actuators for orthoses.

The use of power is not limited to hand function but includes the elbow joint. It was considered that improved designs for elbow joints are necessary.

The use of power, whether body power or external power, also necessitates a stable shoulder to provide a static platform from which to operate a powered system, whether body or external power is used. The Workshop considered the development of a stabilized shoulder joint a high priority.

The panel discussed cosmesis in upper-limb orthotics. The hand is psychologically a highly important part of the body image. Many orthoses which are effective mechanically are unsightly. Cosmesis of hand orthoses needs priority.

The Workshop considers that new designs might displace much of the ungainly impedimenta to a more proximal position where it would be covered by clothing.

Specific recommendations can, therefore, be summarized:

1. That the Veterans Administration should amend its regulations to allow the prescription of custom-made footwear where this is necessary for the proper orthotic management of a foot disability.

2. That the general recommendations on pathomechanical and orthotic mechanics in the general recommendation should be directed particularly to certain specific items.

3. That joint mechanisms and controls for the lower-limb orthoses need to be developed.

4. That elbow and shoulder joints for orthoses need to be developed.

5. That external power systems for orthoses need to be developed.

The Workshop considered the report of the Annapolis meeting, but in the short amount of time was unable to review it. It regarded it as a more detailed report by experts with which the Workshop agreed in general. The Workshop considered it better in the limited time to consider the broader aspects. Even so, there were certain matters not considered.

The adult parapodium is currently having adequate exposure. Similarly, functional electrical stimulation is an important concept. This is also getting adequate attention and did not, therefore, merit use of time in discussion. Neither were omitted from the discussion through ignorance.

UPPER-LIMB PROSTHETICS WORKSHOP

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The workshop group was characterized by high mobility of attending participants throughout the day as many of the members wished to circulate among the various workshops. Nonetheless, it was possible to maintain a reasonably orderly discussion and arrive at certain recommendations. The topics discussed were as follows, not necessarily in the order indicated:

1. Education.
2. Cosmesis.
3. Coordinated control.
4. Specialized centers.
5. Voice control.
6. Components: wrist rotators, interchangeable terminal devices, elbow breakaway — free swing and endoskeletal developments.
7. Maintenance and service.
8. Advanced work on external energy systems, particularly with respect to design tradeoffs, sensory feedback, uses for micro processors.

RECOMMENDATIONS

Education

Experience has shown that much of the difficulty associated with the fitting of both conventional and externally energized prosthetic components and systems has come about because of inadequate education of

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[a] Chairman of the workshop.

prosthetists. The root of the problem is related to the availability of an up-to-date manual of prosthetics densely illustrated with pictorial material depicting the steps of the best available current practices. Development of such material should receive very high priority.

The importance of education in the area of patient selection and prosthetist-patient interpersonal relationships was discussed, and various examples of problems associated with the lack of such education were presented by members of the workshop. It is recommended that the schools institute specific instruction beyond that which is presently given in an aim toward bringing about more effective prosthetist-patient communication.

Cosmesis

Good cosmesis, both from the point of view of the physical appearance of the prosthesis and of motion pattern, has traditionally been a goal with high priority in upper-limb prosthetic practice. Development of new materials leading to endoskeletal arm prostheses has shown that it is feasible to achieve both function and good appearance. Present systems have been somewhat limited by excessively rapid wear and staining of cosmetic coverings, and to some extent with functional limitations such as stiffness at the elbow joint. We have noted that at the present time there is no lockable elbow available for a fully cosmetically covered arm. It was agreed that attempts to make a suitable elbow lock should be encouraged.

It was agreed by everyone present that a high priority should be given the development of an artificial skin that would have properties much superior to the materials currently available. Specifications such as those worked out at CPRD should be the goal of the development.

In relation to the matter of cosmesis, it was conceded that very little hard data exist with respect to amputees' wishes and needs. The trade-off between function and cosmesis is a basic problem that needs continuing research and development effort for both conventional and externally energized arm prosthetic systems.

Coordinated Control

For multi-joint upper-limb prostheses, one of the design aims has been to achieve natural appearing movement dynamics, each joint in relation to the others, with a minimum mental load required by the amputee. Mechanically coupled motions, such as with the Ontario Crip-

pled Children's Center feeder arm and the child's arm developed by Simpson in Edinburgh, have been one design approach. On an experimental basis it has been shown that coupling of motions, equivalent to mechanical coupling, can be achieved with the aid of a programed process control computer. It is recommended that various approaches to coupled motions and the importance for ease in performing routine daily tasks be given additional attention in research and development, and that the OCC and Simpson systems be assessed for the possibility that they could be redesigned into adult sizes to meet VA needs.

Specialized Centers

Substantial discussion concerned the possibility that for high level upper-limb amputation it appeared desirable that specialized fitting centers on a regional basis might better serve the functional regain of the amputee. It was the consensus of the workshop group that such centers would be especially important as more sophisticated applications of external energy are developed.

Voice Control

In a discussion, aided by analysis and suggestions made by Dr. Frank Cooper, it was concluded that voice control for upper-limb prosthetics has very little to recommend it. Aside from complexities and cosmetic limitations in the present and foreseeable state of the art, other contol techniques appear to have more future potential. The advantages of voice control are many under circumstances more complex than those of the high level amputee, and it is recommended that research and development be continued for applications to quadraplegics and certain other high level involvement neuromuscular disorders.

Component Development

The workshop discussed a number of specific components and philosophies for their incorporation into upper-limb prosthetic systems. In particular, it was felt that there may be a need for interchangeable externally energized terminal devices, i.e., hand and hook. At present no externally energized hook is commercially available for adults, although prototypes for these designs have been made, one at Northwestern University and one at the VA Prosthetics Center. Continued development is recommended with the plan that they should be interchangeable with exisiting hands.

The topic of wrist rotators was discussed and it was concluded that it would be highly desirable to have a powered wrist rotator commercially available. It was noted that Otto Bock now sells powered wrist rotators in Europe, but they are not yet available in this country. The possibility of converting the VAPC-Hosmer elbow drive into wrist rotators, as has been done at UCLA, was discussed and generally it was agreed that further development of a wrist rotator should be undertaken along the lines of interchangeability of subcomponents.

The simple elbow break-away and free-swing device which has been developed at Army Medical Biomechanical Research and Development Laboratory should be made commercially available and improved with respect to the requirements for its adaptability for powered limbs. It was pointed out that while the device, as developed, has many good features, including simplicity, its detachment tends to degrade performance by weakening the joint. The consensus was that it is a potentially important development and that it should be made available for testing in its present stage with further improvements planned for the future.

Attention was given to some of the problems of endoskeletal upper-limb systems including the problems of materials, interference with joint motion, durability, etc. As indicated above, it was generally agreed that there is a need for a locking-type elbow in such systems.

Maintenance and Service

Particularly with respect to externally energized systems and high level amputations, sophisticated techniques of maintenance and service are needed. Much improvement can be anticipated by more thorough training of prosthetists and the availability of up-to-date reference materials, but some of the components that are used for myoelectric control for drive trains and power supply may not be repairable in the typical prosthetist's facility. The use of modular design makes it feasible to consider levels of maintenance ranging from minor replacement of modules to major overhauls of the system at certain designated centers. In the United States the economics of supplying two complete systems to each amputee, as is done in Great Britain and Europe, does not appear to be feasible. An alternative of having high priority rapid service should be explored, with the possibility that special mailers could be supplied to each amputee with the object of expediting transportation and time. The consensus of those present at the workshop was that the minimum acceptable time between failures is probably about 6 months, and that practical design should make every effort to better this figure to at least a year. Sponsorship of a special study concerning maintenance and service for both externally energized and conventional prostheses is recommended.

Advanced Work on External Energy Systems

Use of myoelectric control for commercially available powered hands is becoming widely acceptable for the below-elbow amputee. High reliability and virtually unconscious control can be achieved for the function of prehension. The desirability of adding the complication of powered wrist rotation in the below-elbow case is subject to further inquiry before a definite conclusion can be drawn. Refinements in the area of sensory feedback for position and force need more intensive exploration. Multifunctional articulated finger hands such as the Swedish arm appear to be promising, but for reasons of cost and unsolved development problems, such systems are not yet ready for commerical distribution.

For the above-elbow and shoulder-disarticulation case, especially bilateral, problems of supplying usable functional regain remain critical. With the VAPC elbow and the VA-NU hand with either EMG or switch control, the only components that are conventionally available in the U.S., experience has been restricted to date. Hybrid fittings consisting of conventional elbow and powered hand, powered elbow and conventional hook, etc., have produced satisfactory clinical results in a few highly selected cases. The hybrid combinations, in general, appear to be more satisfactory than either fully powered systems or fully conventional systems at this time. It is recommended that additional clinical experience be obtained with various fittings of the available externally energized commercial components in various configurations. It was suggested, as above, that the possibility of developing an adult-sized version of the Simpson arm with its specific control philosophy should be looked into. Also, the Italian experience with the Schmidl system consisting of three powered components—hand, wrist rotator, and elbow— should be critically examined, particularly with respect to fitting and training procedures that could be adapted to VA needs.

Members of the workshop recognized that the ultimate development of upper-limb prostheses depends on available technology, and that advanced technologies in existence today hold the potential for dramatic improvements in functional regain, cosmesis, reliability, and ease of operation. In particular, the technologies associated with pattern recognition, adaptive control, bioelectric measurements, microcomputers, biocompatible materials, and microsurgery warrant close following by the VA for applications to the whole gamut of prosthetic/orthotic and sensory-aid problems. With respect to upper-limb prosthetics, the need is great for substantially more adequate solutions to above-elbow and shoulder-disarticulation amputation. VA contractors at Colorado State University, Northwestern University, and UCLA are engaged in various aspects of application of advanced technology to upper-limb problems. Some of this work, particularly with respect to EMG pattern recognition,

adaptive control, and power train improvements is in the early stages of transition from the laboratory to the clinics. Other aspects, which include advanced filter theory, biocompatible structural materials, and surgical approaches through sensory feedback and motor output stimulation implant devices, remain very close to the laboratory stage at this time. Commercial availability of a powered hand and a powered elbow with various control options and the expectation that a powered wrist rotator may be expected to soon be commercially available provide a sound basis for the promotion of more clinical experience with the VA with alternate configurations of powered components. Experimental systems, such as the Johns Hopkins control and cable drive systems, should be examined in relation to use with presently available conventional and powered components. Overall, with respect to externally energized systems, it is strongly recommended that the VA continue its sponsorship of development work ranging from fundamental studies in the laboratory to extensive clinical testing as a most effective means toward serving veterans' needs for now and into the future.

OVERALL EVALUATION OF WORKSHOP EFFORT

Discussions of the workshop were stimulating and productive. The various contractors became better acquainted with each other, and without doubt communication among the various projects was greatly improved by the workshop experience. Surprisingly little overlap was found among the projects, although in the few cases where overlap was noted it appeared to be fully justified to carry out replications in order to extend mutual experience. Because of the relatively high turnover of the members of the workshop during the day, it was not feasible to systematically exhaust each topic. The recommendations which were made above were the results of what appeared to be a consensus distilled from many comments and views expressed by the workshop participants.

SENSORY-AIDS WORKSHOP

A. Bennett Wilson, Jr., B.S.M.E.[a]

Executive Director, Committee on Prosthetics Research and
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The entire group met during the morning session; split into two groups, one on blindness, the other on hearing, for most of the afternoon; and concluded with a joint session on evaluation.

Because of the enormous scope of the subject matter, it had been felt previously that a "free-wheeling" session in which clinicians and research personnel could introduce their ideas and problems would be more productive than a structured meeting.

During the morning session, the following observations and recommendations were developed.

ACOUSTIC CUES FOR MOBILITY OF THE BLIND

It was suggested by Mr. Gillispie that it might be possible to amplify or otherwise modify ambient acoustic signals to assist a blind person in mobility. In the ensuing discussion it was pointed out that the phenomenon of "facial vision" has been known for some time but that little systematic research had been done in the area. Dr. De l'Aune has done provocative work at the VA Eastern Blind Rehabilitation Center (EBRC) and is organizing a conference to be held in November 1974. The following recommended areas of study were discussed more specifically:

1. A study of the mechanisms found in subjects with normal hearing, with the idea of enhancing these.

2. The development of hearing tests with mobility considered as well as speech comprehension.

3. A study of mechanisms of hearing-impaired subjects with different types of hearing aids.

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[a] Chairman of the workshop.

4. Development of a training program to make subjects aware of available cues.

LOW VISION AIDS

It is recommended that a conference on mobility of subjects with partial vision be held in the fall of 1975.

More research and development is needed for "low-vision" aids in both mobility and reading. However, useful devices that are available do not seem to be deployed effectively.

It was pointed out CPRD had encouraged the American Foundation for the Blind to undertake the responsibility for studying these deployment problems. Apparently, this study has not been initiated, and it was recommended that CPRD follow up on the matter.

It was also recommended that the VA Visual Impairment Service Teams (VIST) be encouraged to become more active in not only dissemination of informatin but also in the collection of information that would be helpful to research, development, and administrative personnel. It was felt that VIST teams might pattern their activities after those of the VA Amputee Clinic Teams.

PREVENTION AND EARLY IDENTIFICATION OF BLINDNESS

It is recommended that each patient, for whatever reason seen by the VA, be examined thoroughly in order to prevent or arrest the development of blindness when possible and to identify cases earlier. The earlier that the onset of blindness can be identified, the less the psychological shock, and consequently the easier will be the transition period and rehabilitation effort.

READING AIDS

It was recommended that the VIST teams be informed once again that the Stereotoner is available for beneficiaries who would like to participate in the evaluation of this device. The VIST teams should also be urged to assist in locating suitable subjects.

It was pointed out that the civilian sector seems to have little problem in locating subjects, and that the younger groups will be the ones who will be more apt to be interested in these types of devices.

Systematic followup on veteran users of the Optacon was recommended.

THE HASKINS SYSTEM

The design of the machines needed for the Haskins reading system is essentially completed and it is recommended that a pilot program, somewhat similar to that proposed by Haskins several years ago, be initiated as soon as possible. It was felt that if the VA does not feel that it can support the entire effort, however, it can encourage and help Haskins to find additional financial support.

HAND-HELD CALCULATORS

Hand-held calculators, which have proven to be so useful to the sighted population, would also be useful to the blind if efficient "read-out" systems can be made available.

It was recommended that a study of the possibilities of such devices be made beginning with a survey of the devices currently available.

HEARING AIDS

CPRD is working on an outline of research priorities for better devices and service to the hearing handicapped.

Research relevant to hearing-aid design improvement should be conducted in cooperation with industry. There is at present insufficient communication between the research and development community and those concerned with practical design considerations.

There is an urgent need for the VA to develop a system for obtaining feedback from hearing-aid users on the effectiveness of their aids in everyday life.

EVALUATION

It was recommended that CPRD advise the Social and Rehabilitation Service and the Office of Education that it would be highly desirable to study the usefulness of the Stereotoner with school-age children.

In general, no new device should be procured in quantity without a plan for its *systematic* evaluation.

GENERAL

Improvement in VA organization is needed for interdepartmental administration and coordination of programs, especially in casefinding, prevention of impairment, and evaluation of aids.

In setting research priorities, goals should reflect a concensus of the best clinical judgment wherever possible, and a system of regular polling of clinicians should be set up.

THE SPINAL-CORD-INJURED PATIENT WORKSHOP

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A delightful group of people participated in the Workshop on the Spinal-Cord-Injured Patient. Everyone contributed and I want to thank the group for their involvement. We talked about many things.

Dr. Radley opened with a few remarks: "In the Veterans Administration Spinal-Cord-Injury Services, 85 percent of the patients were nonservice-connected; generally the result of automobile accidents."

I reviewed some work in which a number of us were involved in January, February, and April 1974, in the area of spinal cord injury. At those conferences, and in the proposal to the Veterans Administration which we were writing, we outlined the areas of investigation which might be necessary in the area of spinal cord injury.

We discussed the concept that the needs of the civilian population are the same as the Veterans Administration needs. Projects which are presently ongoing, not under Veterans Administration support, are under the umbrellas of the universities in departments of neurosurgery, orthopedics, and engineering. Anthony Staros discussed the needs and Veterans Administration Prosthetics Center activities in the area of mobilizers and powered orthoses. Dr. Dudley Childress discussed the activities of daily living, vocational and avocational projects in which he and his group (Prosthetic Research Laboratory and Rehabilitation Engineering Program at Northwestern) had been involved. I discussed the medical considerations of spinal cord injury, bowel and bladder, sex, spinal-cord cooling and so on. Dr. James Reswick with a group from Rancho Los Amigos discussed skin pressure problems with regard to education and devices.

At this recent Workshop we then discussed the definition of prevention as it relates to spinal cord injury. We primarily talked about the prevention of total disability by improved retrieval, transportation, and emergency techniques and management.

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[a] Chairman of the workshop; also Co-Director, Northwestern Memorial Hospital, Superior Street and Fairbanks Ct., Chicago, Illinois 60611

The question was rasied as to neuron regeneration. Where do we stand in that area and should the Veterans Administration be involved in research? My answer is "yes." We discussed engineering capabilities in spinal-cord-injury electronic by-pass systems, as well as surgical nerve graft by-pass techniques.

In the area of mobility aids, we discussed research and the disinterest on the part of the automotive industry in the needs of the spinal-cord-injury patient. The need for automobile industry research and development in the area of vehicle accessories was brought out, I believe, in Sweden. The Volvo Company provides a list of accessories which are applied to their vehicles for the handicapped. Such an interest is needed in our country.

We had indepth discussions on indoor and outdoor mobility aids, whether they be eye, voice, or feedback control systems. We discussed chair restraint and harnessing systems in need of improvement. The state of the art in remote control is now certainly capable of a "Fly by Wire" type of concept, with electric automobile controls from remote switches rather than direct mechanical controls. There is a lack of and a need for redundancy and for safety override systems; there are controls already available for the C-5—C-6 quadriplegic, but there are not yet suitable systems for injuries above that level.

We discussed orthotic devices, primarily those which are on-going, and the experiments in the area of Cleveland with devices and controls for functional electrical stimulation of presently paralyzed muscles. There are advantages and disadvantages in the area of internal versus external systems.

We discussed environmental control or switching units, and again, voice control, eye, touch, and telemetering controls, and a need for an improved positive page turner. Due to the variability of the disability and the need for a large variety of controls, the question is raised, where do we stop on development? No answers were provided.

In the area of skin pressure problems we talked about low level electrical stimulation to decubitus ulcers as being studied in Miami for improvement of healing. We discussed fluid-pressure and other special beds, the needs for powered recliner chairs in the area of mobility aids, and the need for manipulators.

The most positive conversation that came out of our group was in the area of legislation. Disability standards need to be improved in defining who is disabled and how disabled is an individual. What standards have been described for van controls and vans for the transportation of the handicapped? There is a positive need for legislation in the area of employment and disability compensation recognition to avoid the all-

or-none concept. That is to say, the day has long since passed that an individual should be prevented from returning to work simply because he would no longer be handicapped and therefore no longer eligible for VA benefits. One should be encouraged to return to work, perhaps part-time at first, and to be able to continue to receive appropriate disability benefits and compensation, with assurance of resumption of full benefits in case of a relapse.

In the area of education, the obvious need is for engineer-physician interchange. I think this was probably one of the most powerful points expressed. I found great interest in our group that there was almost no discussion of my needs in the area as a surgeon in rehabilitation research and spinal-cord-injury research. The reason is that the engineer has never had the opportunity to be exposed to the problems faced by the surgeon.

We discussed the needs for periodic educational seminars lasting from 4 to 5 or 7 days. Engineering residency programs extending up to 6 months are probably very valid. In these residency programs, solutions to realistic short-term goal activities should be solved by the engineer trainee so that he has an idea of what he is going to be doing when he is in the medical environment.

Lastly, under education we talked about the patient-family allied health education. Certainly we know there are failures, that education systems fail, and that people fail. A fail-safe system should be developed. There is a need for improved education, and there is justification for environmental manipulators by virtue of people failure. Our moderator, Mr. Staros, asked if there is a problem of re-duplication. We do not believe so.

We divide recommendations into two areas, short-term and long-term goals. The definition of short-term is up to 2 years, and long-term is above that period of time. We broke recommendations into four categories: fundamental studies, research and development, clinical evaluation, and education.

Under short-term goals are Fundamental Studies: spinal-cord cooling devices, chemotherapy for spinal-cord trauma, and studies in sensory feedback systems. Under Research and Development we discussed the thermo-electric heat transfer systems which will be capable of being developed in the area for spinal-cord cooling.

An external spine stabilization device will be developed for immediate retrieval, such as rigid foam, dilatancy materials, etc.

In the area of bladder stimulation (micturition control), we talked about magnet-constrictive fluids and bimetallic metal, which might be used for valve systems and bladder control, urinary and micturition

control.

In the area of phrenic nerve stimulation, we discussed the ongoing activities. This area needs to be expanded and further evaluated.

In automotive aids for the handicapped, for both driver and passenger, restraint systems need to be improved; the indoor-outdoor mobility aids need to be expanded. Mobile manipulators or orthoses under voice, eye, or pneumatic control need to be expanded. Mobile environmental controls need to be expanded, and educational modules for reading, such as reading machines and voice compression, all belong to Research and Development.

Under Clinical Evaluation, we discussed again automotive aids, educational modules, and retrieval systems for the Veterans Administration for improved patient retrieval and early reception in spinal-injury centers.

Under education we discussed legislation as reviewed above, employment with benefits, establishment of disability standards, and van standards. Education is needed for the engineer, the medical profession, the patient and the public. We would suggest complex modules to meet immediate needs.

Under the long-term goals, there were four projects that we could define. Under fundamental studies, we talked about spinal bridging, that is, by-passing spinal injury and possibilities for signal reception, unscrambling, and feedback. We talked about nerve graft bypasses and central neuron regeneration. Under Research and Development we discussed the FES systems as they applied to orthoses and speech recognition control units. Under Education, we described legislation for the handicapped, safety standards, compensation, and lay medical education.

Again, it has been a pleasure to participate.

GENERAL DISCUSSION AND CLOSING REMARKS

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As we had hoped, we have succeeded to quite an extent to stimulate interactions between different fields. For example, Dr. Carhart, about to attend a meeting on electrical stimulation of the inner ear, talked with Dr. Dymond about the UCLA critical review of implanted electrodes. A number of people mentioned the speech compressor used by blind sections and its possible modification for use by quadriplegics, which apparently had not been self-evident before. Likewise, the discussion of voice control for quadriplegics presumably has a role for upper-limb prosthetics. The conference has sharpened the focus of application in a number of other devices.

There are a number of common factors among the various groups of projects. Everybody recognized the need for interdisciplinary teams and the importance of education, manuals, and other publications to disseminate information more rapidly to the actual practitioners. In a number of fields, we have heard the same theme of prevention of disability initially and of early detection of patients or people who are at risk of becoming patients. Hopefully, early detection and treatment of circulatory problems may prevent amputation, or at least allow amputation at a lower level. Similarly, early treatment may halt eye disabilities at a point where the patient is only partially sighted but not totally blind.

There has been a fairly common problem throughout the full history of the prosthetics program in finding pilot users among veterans. One amputee veteran, years ago, said in connection with experimental prosthetics problems, "Let the Marines land on that beach head!" He was going to wait until the device was proven as a result of field testing by somebody else. Then, of course, he and other eligible veterans would come in clamoring for it right away. We have very little difficulty in finding civilian nonveteran users, who are going to get careful fitting and a free device as a result of their efforts and participation, assuming

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the device proves to be good. We have a little more trouble in finding a nonservice-connected veteran, and most trouble in finding a suitable service-connected veteran; he knows he is eligible for it anyway, so why should he bother with all the followup involved in participating in the clinical trials?

Reliability has been a common factor in almost all the discussions. We have certainly all been aware of a need for reasonable reliability, but it is good to have this constant emphasis on the problem. We realize, however, that there is no point in engineering a thoroughly reliable boondoggle and then, as soon as it is actually tried on some patients, find that nobody will accept it. We have to start trying new devices on actual patients, samples of the potential users, early in the game when they are relatively risky and not yet very reliable. The mean time between failures may be only a few weeks in some cases, though it should be no more than a few hours. The developer usually has one or a very few "professional" users on his own staff or in his own neighborhood. Then, as the device becomes more reliable (but perhaps still not lasting more than a few months), we start asking for more volunteers and begin larger independent trials. If we waited until we had something that we were sure would last at least 3 years before failure, there would be great risk that it would prove to be a useless device anyway, or that major improvements would be immediately obvious as soon as it was tried on some patients. With such a plan, we would have wasted a lot of time, money, and efforts of talented people.

The question of disability standards and compensations, and some other related matters discussed in workshops are, of course, not in the scope of the prosthetics program in the VA; other people are concerned with those problems. It is perhaps appropriate for us to make suggestions, but please realize that we will not be in a position to do anything directly about them. We will pass on these suggestions to other groups that are appropriately concerned with them. The same comment applies to some of the suggestions on areas which are essentially medical research. We have done some "medical" research in the VA prosthetics program on amputation surgery, on immediate postoperative prosthetic management, on phantom limb pain, or on a number of other areas where we pioneered through some of our contractors. We were delighted that either the VA medical research program, NIH, or someone else picked up some of these areas with the much greater support that was needed for long range research on clearly medical problems.

In turn, then, the prosthetics program sometimes becomes involved with the development of or with the dissemination of devices arising out of the VA medical research program. The cardiac pacemaker was a case in point. One of the pioneers was Dr. Chardack at the VA Hospital at Buffalo, supported by the medical research program which was under

Dr. Newcomb's predecessors. Eventually, when the pacemaker became a routine item, the prosthetics representatives in the field bought the pacemakers for their local surgeons to implant.

Dr. Meyer has a very interesting point that where the engineer has not been exposed to direct contact with patients, he does not recognize problems suitable for engineering attack. This has been true in many areas. We hope this meeting has been successful in exposing not only the engineers and inventors of the prosthetics program to areas they had not thought about before, but also in stimulating potential interdisciplinary interaction in other areas. We would be happy to have any discussions and suggestions, not only from conference participants, but also from readers of the Bulletin of Prosthetics Research as well.

There are a number of acknowledgments that are in order in closing. Particularly, I would like to start with William Bernstock, our distinguished consultant, retired Assistant Chief, R & D Div., Prosthetic and Sensory Aids Service, former Editor of the Bulletin of Prosthetics Research, and still a member of its Editorial Board. He was the man who originally suggested the idea of this conference. I am delighted that he is able to be here to see the realization of his idea.

Our own VA people include Dr. Radley who is chairman of this event, Mr. Lewis, Mr. Freiberger, Mr. Conners, and a number of the people who we left back in New York. Our secretaries have all been extremely helpful. We look forward to Howard Freiberger continuing his careful work in getting the documents together. Mrs. Beiser, Mrs. Sowell and Ms. Berzins will do literary and technical editing as rapidly as feasible. Mr. Cortright, who is our representative on Dr. Newcomb's staff, has been very helpful in organizing this meeting and expediting its conduct. He has been in and out of the conference room and working with the staff of the Northwestern University groups to have documents reproduced, lists prepared, and all kinds of details handled to contribute to the smooth running of the meeting.

It is clear that the VA Prosthetics Center staff, under Mr. Staros, have been involved. Mr. Staros has participated not only in his key role as cochairman of the meeting and moderator of a major session, but also in providing a total of nine participants for the meeting. VA Prosthetics Center people have contributed as speakers and have been distributed through all the workshops. They had done a great deal of the initial planning, drafting of the agenda, etc., as well.

Mr. Wilson of the CPRD both has helped plan the agenda and has provided people from his own staff. He, Miss Young, Dr. Haas, Dr. Harris, and Dr. Sharples have been very helpful. Naturally the value of the conference depended on the contributions of each project leader, not only in reporting his own work but also in discussing efforts of others.

Again, we are very grateful to Dr. Compere, the Northwestern University projects, and the Rehabilitation Institute of Chicago for their hospitality.

NOTES AND NEWS

DR. MARIAN WEISS LECTURES ON MANAGEMENT OF THE SPINAL CORD INJURED AT NEW YORK VA

Dr. Marian Weiss, Director of Stocer Rehabilitation Center, Warsaw, Poland, visited the Veterans Administration at 252 Seventh Ave., N.Y.C., on Tuesday, November 19, 1974. He lectured to members of the VA Prosthetics Center and the Research Center for Prosthetics in New York City on the treatment and rehabilitation of the spinal-cord-injured patient.

Dr. Weiss presented his concept of optimum patient treatment and rehabilitation achievable through a highly organized and concentrated team effort. Using slides and films, he described how traumatized victims are rescued immediately from the scene of the accident by an emergency van or helicopter. On arrival at his center, the patient is examined and X-rayed. If fracture-dislocation is present, surgical stabilization is performed immediately. Dr. Weiss described his technique of using a spring attached to a transverse process of one vertebra several vertebra above the fracture dislocation, and then attaching the other end of the spring to a transverse process several vertebra below the fracture dislocation. The day following surgery the patient begins an intensive program of physical therapy, including vertical tilting and passive exercises. Two weeks after surgery, the patient is fitted with specially designed orthoses and begins ambulation. He continues on a program of physical therapy for 2-3 months. Additional rehabilitation includes vocational guidance, if necessary.

Dr. Weiss pointed out that this method of early management has decreased the occurrence of decubiti, has decreased the incidence of vascular and urinary problems, virtually has eliminated flexor spasticity, and has contributed greatly to the psychological and social rehabilitation of the spinal-cord-injured patient.

NEW VA AMPUTEE TREATMENT CENTER OPENS IN DENVER

The twentieth VA amputee treatment center in the nation opened

recently in Denver, Colorado. The new center includes a prosthetics clinic team, which evaluates each patient's needs, prescribes prosthetic devices as required, and fits temporary limbs, and an orthotic laboratory, which makes individually designed braces and completes adjustments and repairs. Much of the final work on artificial arms and legs is contracted out to local manufacturers in the Denver area.

The other VA Amputee Treatment Centers are in Seattle, Chicago (West Side Hospital), Albuquerque, Atlanta, Boston, the Bronx, N.Y., Buffalo, Cleveland, Dallas, Houston, Los Angeles, San Francisco, Louisville, Miami, Memphis, Minneapolis, Richmond, St. Louis, and Wood (Wisconsin).

ASTM FORMS COMMITTEE ON ORTHOTICS AND EXTERNAL PROSTHETICS

The American Society for Testing and Materials formed a new ASTM Committee, F-19 on Orthotics and External Prosthetics, at the Society's Philadelphia Headquarters on September 16, 1974.

The committee plans to encompass the development of the following: definitions of terms and nomenclature, specifications, methods of testing, and materials (including basic and component materials) for orthoses, external prostheses, and patient aids and their application.

These developments are to be carried out by seven subcommittees that will specifically cover materials and design; structural integrity (orthoses, prostheses, patient aids); design criteria; safety; cosmetics; application (education, prescription format, patient orientation, use of criteria); and nomenclature (terminology and definition, prescription format, application).

The officers of the committee are: Chairman, Paul R. Meyer, Jr., M.D., The Rehabilitation Institute of Chicago, Chicago, Ill.; vice-chairman, Thomas Pirrello, Veterans Administration Prosthetics Center, New York City; recording secretary, Peter Nelson, National Academy of Sciences, Washington, D.C.; and membership secretary, Ralph Storrs, Pope Brace Co., Kankakee, Illinois.

Those interested in participating in the committee's activities should contact: Peter Brown, ASTM, 1961 Race Street, Philadelphia, Pa. 19103, Tel. 215-569-4200.

SPECIAL VANS DRIVEN BY PARALYZED VETS FROM N.Y. TO WASHINGTON, D.C.

Paralyzed veterans recently drove four specially adapted vans from

New York to Washington, D.C., at normal highway speeds and without police escort.

The vans used in the New York to Washington motorcade are designed so that paraplegics and quadriplegics can operate them without leaving their wheelchairs. Lifting devices enable them to enter and leave the vehicle, and special hand mechanisms replace the normal foot controlled pedals. Each of the participating paralyzed veterans was licensed and experienced in the use of automotive vehicle hand controls.

Representatives of the Paralyzed Veterans of America, who are cooperating with VA in the program, accompanied the motorcade and demonstrated the vans in front of VA's Central Office and on Capitol Hill. Administrator of Veterans Affairs Richard L. Roudebush was host to the Washington visit (Fig. 1).

Among the legislators on Capitol Hill inspecting the vans were Senators Vance Hartke, chairman, Strom Thurmond, and Robert T. Stafford of the Senate Veterans' Affairs Committee, and Representative John P. Hammerschmidt, ranking minority member of the House Veterans' Affairs Committee.

FIGURE 1.—Shown in front of VA Central Office are Deputy Administrator Odell W. Vaughn (left) and Administrator Richard L. Roudebush (right) with some members of a motorcade that drove from New York to Washington, D.C. The 500-mile trip was made in the specially adapted vans shown, and the vans were driven by severely paralyzed veterans.

This demonstration, the first of its kind, was part of a VA evaluation and training program to gain field experience with the various systems that enable the physically handicapped to drive. The driver-aid innovations have been under test by the VA for more than 1 year at the VA Prosthetics Center in New York City. The vans are scheduled for additional testing and analysis at 13 VA Spinal Cord Injury centers across the nation.

BIBLIOGRAPHY PUBLISHED ON ARCHITECTURAL BARRIER-FREE DESIGNS FOR THE HANDICAPPED

The Paralyzed Veterans of America (PVA) has recently published an annotated bibliography, *Barrier Free Design: A Selected Bibliography,* intended to influence design and construction professionals to a greater awareness of public needs. Compiled by Peter Hassen, PVA's National Architectural Coordinator, the 103-page book is the most extensive bibliography ever published on architectural design with accessibility for the handicapped in mind. Categories included among the 22 headings are: Standards and Specifications, Human Factors, Planning, Checklists, Transportation, Bathrooms, Kitchens, etc.

The book is available for $6.00 from the Michigan Chapter Paralyzed Veterans of America, 5646 McMillan, Dearborn Hts., Michigan 48127.

PEDORTHIC FOOT SYMPOSIUM HELD IN NEW YORK CITY

The first tri-state Pedorthic Foot Symposium, sponsored by the Prescription Foot Association and assisted by the VA Research Center for Prosthetics, was held at the Commodore Hotel, New York City, on September 30-October 4. The symposium is one of a growing number of efforts in the PFA's program for continuing education on prescription shoe fitting, both for the interested public and for those experienced in the field.

The conference centered on the pathology, diagnosis, and treatment of the foot, with emphasis on orthoses and prescription footwear as means of treating foot problems. Further discussion involved aspects of gait analysis and matters of the lower limb. Among the faculty were Dr. Gustav Rubin of VAPC, New York, and Mr. Roddy Chupurdia of VAH, Los Angeles (Wadsworth), California.

The New York Veterans Administration was active in planning and presenting the program. The Orthopedic Shoe Service, VAPC, conducted a tour of their facility, and Dominick Bonarrigo and other staff members of the Orthopedic Shoe Service, VAPC, presented a detailed analysis of various shoe modifications, and were hosts for a tour of the VAPC Orthopedic Shoe Service facility.

FAA PROPOSED AIR TRAVEL REGULATIONS OPPOSED
BY EASTER SEAL SOCIETY

Proposed Federal Aviation Administration regulations on air travel for the handicapped have drawn sharp opposition from the National Easter Seal Society for Crippled Children and Adults. Under the proposals, airlines could refuse passage to a handicapped person unless accompanied by an attendant or carrying a doctor's statement signed within the preceding 6 months, certifying that the traveler could evacuate a plane without assistance.

Easter Seal Society contends that the added cost of an attendant would make flying too expensive for most handicapped people and would cause those who must travel in their work to lose their jobs. In addition, the Society's President, A. Clay Stewart, has told the FAA that many handicapped persons will find it difficult to obtain a doctor's certificate, since doctors may fear malpractice suits in the case of a plane accident.

Easter Seal Society finds controversy with the FAA's definition of "handicapped" as any person who needs the assistance of another "to expeditiously move to an emergency exit in the event of an emergency evacuation."

Easter Seal Society argues that this definition discriminates against people with visible mobility problems while ignoring individuals whose disabilities are not as apparent, such as those with severe emotional problems, mental retardation, heart conditions, and epilepsy. In addition, the proposals specifically exclude the deaf and the blind from the definition of handicapped. Easter Seal Society adds that the definition is so general that "the decision as to who is handicapped will continue to be made on a subjective basis . . . by airline personnel." Many people, including the temporarily disabled, the elderly, and pregnant women, may be considered handicapped by one airline and not by another and will not know until boarding time whether or not they will be able to fly.

The Easter Seal Society, the largest voluntary agency serving the handicapped, urges the FAA to further study the problems of air travel for the handicapped before instituting the new regulations. In addition, the Society asks the FAA to consider modifications of plane design to insure the safety of all passengers and urges the FAA to implement accessibility standards for air carriers to make them more available to the physically handicapped.

LOYAL E. APPLE APPOINTED NEW AFB EXECUTIVE DIRECTOR

Loyal Eugene Apple, Chief of Western Blind Rehabilitation Center, VAH, Palo Alto, California, has been named executive director of the American Foundation for the Blind, effective January 1975.

He succeeds M. Robert Barnett, who retired after 25 years in that position, and who also retired as executive director of the American Foundation for Overseas Blind. Succeeding Mr. Barnett in the latter position is Harold G. Roberts, associate director for service of the American Foundation for the Blind.

Mr. Apple has been director of the Western Blind Rehabilitation Center, since 1967. From 1960 to 1967 he was chief of the Central Blind Rehabilitation Section at the Veterans Administration Hospital, Hines, Illinois. Previously he had been field representative and then director of the national field service program of the Blinded Veterans Association.

Born in 1932 at McCurtain, Oklahoma, Mr. Apple spent his school years in Independence, Mo., and graduated from William Jewell College, Liberty, Mo., in 1952. His postgraduate studies include work at Southern Baptist Theological Seminary, Louisville, Ky., Western Michigan University, Kalamazoo, Michigan, and the College of Notre Dame, Belmont, California. He was blinded in a training accident while serving with the U.S. Army in November 1955. Mr. Apple is married and has three children.

Mr. Barnett, who will live in Florida, will continue to serve both Foundations as a consultant.

W.G. HOLSBERG HONORED BY BVA

Mr. Wilfred G. Holsberg, Chief, Prosthetics Field Operations Staff, Surgical Service, Department of Medicine and Surgery, VA, was awarded a BVA Certificate of Appreciation at the 29th National Convention of the Blinded Veterans Association on August 9, 1974. The presentation was made in Denver, Colorado, by the organization's national president, Mr. Clyde W. Waugh. The citation on the award recognizes Mr. Holsberg "In grateful recognition of an outstanding contribution to the welfare of Blinded Veterans."

SENATOR JACOB K. JAVITS AND ALEXANDER F. HANDEL RECIPIENTS OF 1974 MIGEL MEDAL

The annual Migel Medal, presented by the American Foundation for the Blind (AFB) for outstanding service in work for the blind, was awarded this year to Senator Jacob K. Javits of New York and Alexander Handel, executive director of the National Accreditation Council for Agencies Serving the Blind and Visually Handicapped. The men received their awards on October 24 at the AFB headquarters in New York.

The medal, established in 1937 to honor the late M.C. Migel, first president of the Foundation, is designed to recognize professionally

employed practitioners in education, rehabilitation, and social welfare concerned with blind persons and lay persons who have voluntarily dedicated themselves to advancing services for blind persons.

Senator Javits, as a vigorous proponent of governmental programs which have helped handicapped persons, received the layman award. His accomplishments in the area of rehabilitation legislation have included bills to improve disability insurance cash benefits for blind persons; the Rehabilitation Act of 1973, which encourages hiring the handicapped in federally funded programs; and the recently passed Javits-Wagner-O' Day Act which provides for preferential purchase by the Federal Government at a fair market price of products and service provided by workshops for the blind and for other severely handicapped persons.

Mr. Handel is receiving the professional award for his major role in the establishment of the National Accreditation Council for Agencies Serving the Blind and Visually Handicapped (NAC), of which he has been executive director since its founding in 1967. He was executive director of the Council's predecessor organization, the Commission on Standards and Accreditation for Services for the Blind (COMSTAC), from 1964 through 1966.

ENGLISH LANGUAGE EDITION OF BOOK ON THE EEGs OF BLIND PERSONS PUBLISHED

An English edition of an original 1967 Russian study, *Blindness and the Electrical Activity of the Brain: Electroencephalographic Studies of the Effects of Visual Impairment,* has recently been issued by the American Foundation for the Blind.

The study by L.A. Novikova, who is on the staff of the Institute of Defectology of the Soviet Socialist Republic, Moscow, demonstrates the remarkable ability of the human brain to adapt to and compensate for extreme sensory deprivation. It is a unique study in its attempt to measure, quantitatively, the effects of sensory impairment, particularly loss of or lack of vision, on a large group of both humans and animals using the electroencephalogram (EEG).

The English translation is by Bernard Sznycer and Ludmila Zielinski, and is edited by Zafja S. Jastrzembska, assistant director of AFB's International Research Information Service. The book is illustrated and includes tables and references. The price is $5.75 per copy.

RECENT PATENTS [a]

Angle Adjustment Unit for Prostheses and Orthoses: Franz Gelbenegger. An angle adjustment unit for the angular positioning of a prosthesis or orthosis member with respect to a conventional prosthesis joint. It consists of a commercial ball-and-socket joint coupled to the conventional prosthesis joint by means of a rod extending the ball-and-socket joint and projecting at a free end portion into the prosthesis member. The prosthesis member may be locked in any desired angular position with respect to the conventional prosthesis joint. (Patent No. 3,790,965, Feb. 12, 1974; filed July 26, 1972, Appl. No. 275,434; 3 claims.)

Gravity Activated Prosthetic Device: Russell S. Crapanzano. A prosthetic device especially for use as an artificial arm and hand. An electrical device operates grasping elements at the outer end of the prosthetic device. The flow of electrical current to the electrical device is in turn controlled by mercury switches. The switches are positioned so that the position and orientation of the prosthetic device determines whether or not current is transmitted to the electrical device to operate the grasping elements. (Patents No. 3,683,423, Aug. 15, 1972; filed Jan. 19, 1971, Appl. No. 107,791; 20 claims.)

Hydraulic Flexion Control Device: Charles M. Scott, Assignor to the United States of America as represented by the Secretary of Health, Education, and Welfare, Washington, D.C. A hydraulic knee flexion control device which when unlocked is completely flexible and free to align with the knee joint axis. It is comprised of a rectangular cross-section spring wound tight with a flexible cable positioned in the center of the spring. A hydraulic system holds the cable immovable when the joint is to remain rigid and lets the cable extend permitting the spring to bend when flexion is desired. The object of the invention is to provide a polycentric knee joint for knee-ankle-foot (KAFO) orthosis. (Patent No. 3,799,159, Mar. 26, 1974; filed Oct. 28, 1971, Appl. No. 193,327; 9 claims.)

Knee Brace: Harris L. Gardner. A knee brace which has a perforated upper and lower member coated with a soft plastic material and adapted to take the form of and to be secured to the leg of the user above and below the knee. A semiball joint attaches the upper and lower members and provides free pivotal rotation while restricting lateral rotation. Reinforcing ribs are formed on the upper and lower members to provide rigidity along a line parallel to the leg. (Patent No. 3,799,158, Mar. 26, 1974; filed Oct. 6, 1971, Appl. No. 187,021; 2 claims.)

Motorized Wheelchair: Donald Chisholm. A motorized wheelchair comprising a pair of removable armrests and a backrest that will pivot forward from an upright position into one in which it flattens against the seat to overlie the same and minimize the vertical clearance space required by the wheelchair when it is loaded into a vehicle or other restricted space. (Patent No. 3,807,520, Apr. 30, 1974; filed Dec. 15, 1971, Appl. No. 208, 290; 4 claims.)

Orthopedic Heel: Thomas D. Hall. An orthopedic heel is provided which is particularly suitable for correcting internal tibial torsion or hip anteversion. The heel is designed to provide a rotational stress to the leg of the wearer during walking without providing stress to the foot when standing. (Patent No. 3,804,099, Apr. 16, 1974; filed Mar. 5, 1973, Appl. No. 338,393; 5 claims.)

Page Turning Device: William Jacobus Kroes, Assignor to Stichting Revalidatie Research, Schiedan, Netherlands. A page turning device for mechanically turning the pages of a book comprising holding means for holding the book and a suction mouth for lifting in the page. The suction mouth is so positioned that the plane of its open end encloses an acute angle with the part of the page remote from the hinge line of the book so as to effect a better separation of the lifted page and the subjacent one. A transparent disk having a cutout rotates between the lifted page and the book, takes the page along, and turns it completely. (Patent No. 3,800,453, Apr. 2, 1974, filed July 3, 1972, Appl. No. 268,584; 4 claims.)

Stand-up Wheelchair: Charles M. Weant and Arthur Schwartz, assignor to Arthur Schwartz, Edgewater, Md. A wheelchair including motor-operated means for raising and lowering a partially paralyzed person from a seated to a standing position. The same motor provides propelling means while in both its lowered and raised position. Suitable means are provided for restraining the patient in the chair when in the standing position to provide support. (Patent No. 3,807,795, Apr. 30, 1974; filed Mar. 20, 1972, Appl. No. 236,268; 14 claims).

Telescopic Stick for Paralytics: Arthur J. Cloran. A telescopic mouth-held stick for paralytics consists of a mouthpiece for retention in the mouth covering the crowns of all the teeth. The mouthpiece supports a telescopically extensible stick and an actuating mechanism. Control means for extending or retracting the stick are incorporated in the mouthpiece and/or on the actuating mechanism so that the patient may conveniently adjust the length for typing, controlling wheelchair switches, turning pages of books, or the like. (Patent No. 3,795,281, Mar. 5, 1974; filed June 5, 1972, Appl. No. 259,783; 6 claims.)

Universal Wrist System: Wesley C. Prout, Assignor to Park, Davis and Company, Detroit, Mich. A universal wrist system in which terminals with different types of shafts and different types of mountings may be used. A wrist forearm connector member is adapted to be molded into a prosthetic forearm. (Patent No. 3,798,680, Mar. 26, 1974; filed Apr. 5, 1972, Appl. No. 241,221; 12 claims.)

Wheelchair Assembly and Body-Supporting Insert Therefor: Lola Alson. A removable body support insert for a wheelchair frame, having a head and back portion including side restraints; a buttock, knee, and leg portion; and an optimal adjustable foot portion. A separate bolster may optionally be inserted beneath the knee-supporting portion. (Patent No. 3,792,897, Feb. 19, 1974; filed Oct. 8, 1971, Appl. No. 187,736; 5 claims.)

PUBLICATIONS OF INTEREST

BOOK REVIEW

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SPINAL CORD INJURIES
Comprehensive Management and Research
Professor Sir Ludwig Guttmann
Blackwell Scientific Publication
Oxford, London, Edinburgh, Melbourne, 694 pp., 1973

This book is the personal record of the author's pioneering efforts in the care of the spinal-cord-injured patient and his development of Stoke Mandeville as a spinal-cord-injury center. He traces the development of the center from its initiation in 1944 with one patient to its present position as one of the world's outstanding facilities for the care of patients with spinal cord trauma.

The text is thorough in most instances, particularly in the author's treatment of the urologic problems and other clinical aspects associated with spinal cord injuries. Included are detailed analyses of the major problems encountered in a spinal cord center: the effects of the disturbance in metabolism on the calcium and protein balance, osteoporosis, soft tissue calcifications, pressure sores, bowel care, vasomotor problems, respiratory problems, and indications for surgical intervention.

Each point made and conclusion drawn is illustrated by one or more case histories; the author refers frequently to the extensive literature in the field. Reasons for his disagreement with others are specifically detailed. For example, the author states that many surgeons still carry out immediate or early decompressive laminectomy. He not only quotes his own experiences in disagreeing with this procedure, but also quotes Comarr that twice as many patients without laminectomies (31 percent) showed improvement when compared to those who did (15.5 percent).

This book does have surprising omissions. For example, there is no description of the use of external power for the upper limb of the patient with partial or complete cervical level injury, nor of the work being done in the area of remote manipulators for the tetraplegic. Neither is mention made of the rapid development in recent years of environmental

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controls, nor of games for the tetraplegic. There is, however, an excellent section on games for the paraplegic.

The author also makes some controversial statements. For example, "In *most* (italic supplied) paraplegics, even those with complete lesions of the upper thoracic and lower cervical cord, walking capabilities can be restored to variable degrees." This would appear to disagree with the Rancho Los Amigos viewpoint as set forth by Hussey and Stauffer, who stated that "only exceptional patients with levels of injury above T12 could obtain any form of functionally significant ambulation." ("Spinal Cord Injury Requirements for Ambulation." Arch. Of Phys. Med. and Rehab., Vol. 54, p. 544, Dec. 1973). Rossier, in his excellent monograph on *Rehabilitation of the Spinal Cord Injury Patient* (Documenta Geigy, Acta Clinica, No. 3, North American Series, p. 87), states: "Paraplegics are too often required to make heroic efforts to achieve results which, while spectacular and impressive in themselves, cannot be repeated daily during a working life whose ordinary needs are already fatiguing for a normal person. For this reason it is unrealistic to try to teach a complete paraplegic with a lesion above T11-T12 either swing-through or four-point alternating crutch gait as a *practical* method of ambulation." Perhaps the author's qualifying adjective "variable" modifies his statement in the same manner that the classification of Hussey and Stauffer (vide supra) modifies their definition of ambulation, that is the division of "ambulatory" function into community, household, exercise, and nonambulatory.

The faults are relatively minor, the illustrations excellent, the text highly readable, and the editing oversights miniscule. It includes numberous references to significant personal observations made by the author, and indicates in detail the manner in which he developed his approach to treatment of the spinal cord injured. This book will undoubtedly become rapidly established as a standard text and reference work in the area of spinal cord injuries. It fulfills the expectations aroused by the all-inclusive subtitle, and will be a lasting tribute to the author.

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SENSORY AIDS

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CALENDAR OF EVENTS

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American Society of Mechanical Engineers, Summer Applied Mechanics Conference, Rensselaer Polytechnic Institute, Troy, N.Y., U.S.A. June 23-25, 1975.

The American Orthopaedic Association, Hot Springs, Va., U.S.A., June 23-26, 1975.

The Fifth International Congress of Biomechanics, Jyväskylä, Finland, June 29-July 3, 1975.

Thirteenth Congress of the International Society of Orthopedic Surgery and Traumatology, Copenhagen, Denmark, July 6-11, 1975. (For information: S.I.C.O.T., 43 rue des Champs Elysees, 1050, Brussels, Belgium.)

Seventh World Congress of World Federation of the Deaf, Washington, D.C., U.S.A., July 31-Aug. 7, 1975. (For information: Frederick C. Shreiber, Executive N.A.D., 905 Bonifant St., Silver Spring, Md. 20910, U.S.A.)

International Congress on Education of the Deaf, Tokyo, Japan, Aug. 25-29, 1975.

Twenty-Eighth Annual Conference on Engineering in Medicine and Biology, sponsored by Alliance of Engineering in Medicine and Biology, Fairmont Hotel, New Orleans, La., U.S.A., Sept. 20-24, 1975.

Optical Society of America, Sheraton Hotel, Boston, Mass., U.S.A., Oct. 20-24, 1975.

The National Assembly of the American Orthotic and Prosthetic Association, Fairmont Roosevelt Hotel, New Orleans, La., U.S.A., Oct. 29-Nov. 1, 1975.

Fifth Pan Pacific Conference on Rehabilitation, Singapore, Nov. 2-7, 1975. (For information: Singapore Council of Social Service, 11 Penang Lane, 5th Floor, Singapore 9.)

American Speech and Hearing Association, Washington, D.C., U.S.A., Nov. 21-24, 1975.

American Society of Mechanical Engineers, Winter Annual Meeting, Sheraton Lincoln-Regency Hyatt Hotels, Houston, Texas, U.S.A., Nov. 30-Dec. 5, 1975.

Second Conference on Prosthetics, France, Spring 1976. (For information: World Veterans Federation, 16 rue Hamelin, Paris 16, France.)

Seventh International Congress of Physical Medicine and Rehabilitation, Rio de Janeiro, Brazil, Aug. 1-6, 1976. (For information: Dr. J. Rezende, 126 Av. Franklin Roosevelt, 5' Andar, 20000 Rio de Janeiro, Brazil.)

Combined Meeting of the Orthopaedic Associations of the English-Speaking World, London, England, Sept. 12-18, 1976.

The National Assembly of the American Orthotic and Prosthetic Association, Diplomat Hotel (held jointly with Interbor), Hollywood, Fla., U.S.A., Oct. 20-23, 1976.

American Speech and Hearing Association, Houston, Tex., U.S.A., Nov. 18-21, 1976.

The National Assembly of the American Orthotic and Prosthetic Association, Sheraton Palace, San Francisco, Calif., U.S.A., Oct. 26-29, 1977.

American Speech and Hearing Association, Chicago, Ill., U.S.A., Nov. 2-5, 1977.

Second Congress of the International Society for Prosthetics and Orthotics, United States of America, 1977 (For information: International Society for Prosthetics and Orthotics, P.O. Box 42, DK 2900, Hellerup, Denmark.)

The National Assembly of the American Orthotic and Prosthetic Association, Town and Country Hotel, San Diego, Calif., U.S.A., Oct. 31-Nov. 4, 1978.

SENSORY-AIDS EXCERPTS FROM BPR 10-22
ON TAPE CASSETTES

"Sensory-Aids Excerpts from the Bulletin of Prosthetics Research, BPR 10-22 Fall 1974," available on tape cassette include the following items:

VA Conference of Prosthetics and Sensory Aids Research Project Leaders.

G.D. Causey: Hearing Aids and the Veterans Administration

H.L. Lauer: Reading Aids for the Blind

H. Freiberger: Mobility Aids for the Blind

H. Freiberger (Moderator): Sensory Aids

R. Carhart: Research on Hearing Aids Design

G.D. Causey: Hearing Aids

H.A. Mauch and G.C. Smith: The Development of Personal Reading Machines for the Blind

M. Butow: Teaching the Stereotoner, Its Problems and Rewards

R.A. Weisgerber: The Development of Living Skills by the Handicapped

F.S. Cooper: The Current Status of Reading Machine Research at Haskins Laboratories

J.M. Benjamin, Jr.: The Laser Cane

J.D. Malamazian and H. Lauer: Current State of the Research Effort at Veterans Administration Hospital, Hines, Illinois

L.E. Apple: Current State of the Research Effort at the Western Blind Rehabilitation Center

G.M. Gillispie and W. De l'Aune: Research at the Eastern Blind Rehabilitation Center

A.B. Wilson, Jr.: Workshop Panel on Sensory Aids

Notes and News

Loyal E. Apple Appointed New AFB Director

W.G. Holsberg Honored by BVA

Senator Jacob K. Javits and Alexander F. Handel Recipients of 1974 Migel Medal

English Language Edition of Book on the EEG's of Blind Persons Published

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